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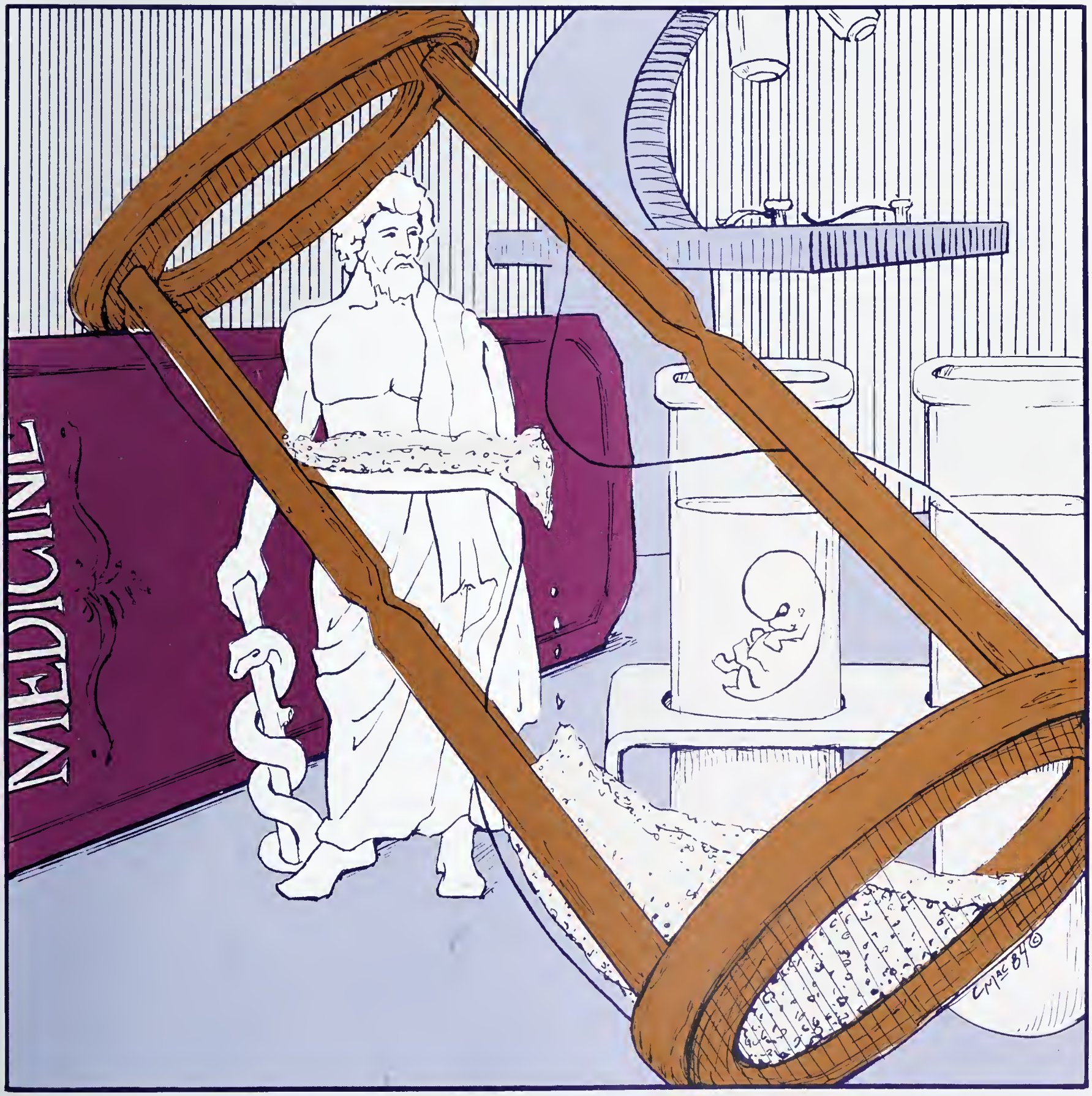

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Techniques, Ethics, and Legal Perspectives

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1) All articles intended for publication should be submitted to the editors before the deadline which is usually six weeks before the release of the Journal.
2) Submitted articles should be typed (or legibly printed) double-spaced, single-sided on paper 8½" x 11" (letter size) and they should not be more than 20 to 30 pages (5000 to 6000 words).
3) Illustrations, graphs, diagrams and figures should be put on a separate sheet and identified by Arabic numerals. A list of explanatory legends for all the figures and diagrams should be put on another sheet. Do not write on the back of photographs.
4) References should be checked with the original sources, designated by raised Arabic numerals in the text, and listed in alphabetical order on a separate sheet. Each periodical reference should include in order: the author's last name and initials, title of the article, journal name, volume number, page number, and year (e.g. Risser JC: Scoliosis: Past and Present. *J. Bone and Joint Surg* 46 A:167, 1964). For further information please consult the MLA Stylesheet.
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MEDICAL PRACTICE BUSINESS PRACTICE

FROM THE FRONT DESK

Medicine as a Human Science

Anne Wong 8T6

"I chose medicine because I want to help people". It is sad that matters have reached a stage where in many cases, the immediate response to this statement is a cynical, "And the money isn't bad either." Certainly the side benefits of practising medicine are substantial, but they should not detract from the real aims of medicine — the concern and caring for the health of a fellow human being. Indeed, it is becoming harder and harder for a person who sincerly believes in "Medicine as a Human Science" to sound sincere. The phrases to express this belief have become clichés which, in this age of cynicism, either conjure up the stereotype of the "bleeding heart" with the grandiose plans of saving the world or of the ambitious, "money-grabber" hiding under a sheep's clothing of altruism. These phrases have become so hollow-sounding that it is easy to forget their essential validity. The values they express are timeless. It is never "old hat" to restate and remind oneself of them.

It has been said that an inevitable transition that a medical student undergoes is one of "naive idealism" to one of "wise cynicism". The merciless grind of the medical system is such that the student undergoes emotional hardening almost as a necessary psychological defence against the academic demands, personality differences, tragedies and other stressful situations he or she encounters in the hospital or class. The issue here is not whether emotional hardening occurs or not — it does in all to some degree — but rather, the issue is on the extent of hardening. The danger lies in the loss of perspective and sensitivity which results in viewing the patient primarily as a *person* with a problem. To take the former approach would be to negate the very aims of medicine. The medical system can mold the individual only so much — the type of physician he eventually becomes is ultimately his own responsibility.

It is ironic that although physicians and students spend a great deal of their time in the hospital, relatively few have been in the hospital for a significant illness. Perhaps only at that time would he or she truly appreciate how the "other half" lives — the depersonalization, stripping of social status, uncertainty, fear and utter vulnerability experienced in the health care system. Every individual jealously guards his autonomy, his privacy, and the right to control his own life. To be admitted into the health care system. every individual jealously guards his autonomy, his privacy, and the right to control his own life. To be admitted into the health care system is to relinquish this control. The physician, in many cases a complete stranger, is allowed access to the patient's body, to the most personal details of his life and most private of emotions, information which could very well be revealed to no one else. The physician must appreciate how hard it is to give up one's autonomy, and the privileged position he is placed in when a patient does entrust to him the care of his person. Such a responsibility demands that the physician reciprocate with sincerity, care and respect.

No matter how many cases of appendicitis, lung cancers or myocardial infarcts a physician (or student, for that matter) sees, he must remember that although the problem is not unique for him, it is exquisitely unique for the patient and may have widespread ramifications. Disease is a two-way street — it always involves the psychological as well as the physiological aspect. In view of this the only effective treatment is one which is implemented with the understanding of the pathophysiology in the context of the human being. Not only is such treatment more effective, as it aims for the root, not the branch, it is also time-saving in the long run by minimizing problems of patient noncompliance, misdiagnosis, and mistreatment. Taking the stance that medicine aims to care for a fellow human being means increased *quality* of interaction with the patient, not, necessarily, increased quantity.

We, in the medical profession are in a unique and enviable position. Unlike other fields, such as research, in which the individual wanting to help society may be frustrated by the length of time, the relatively smallness of his individual contribution, and the tangential nature of his work, medicine allows the individual to directly help many, with tangible and often gratifying results.

It is sad that medicine has been at the centre of so many controversies (The Canada Health Act, doctor strikes and trials, rising fees, etc.) and, yes, so many derisive clichés, that its *raison d'etre* has been obscured. I invite you to look back to your earlier days and remind yourselves of why you started on this path in the first place. To me, medicine is first and foremost, a *Human* science, whether spelt with an "e" or not.□

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RADIOLOGY ROUNDS

Diagnostic Challenge

Bernard Boulanger 8T5

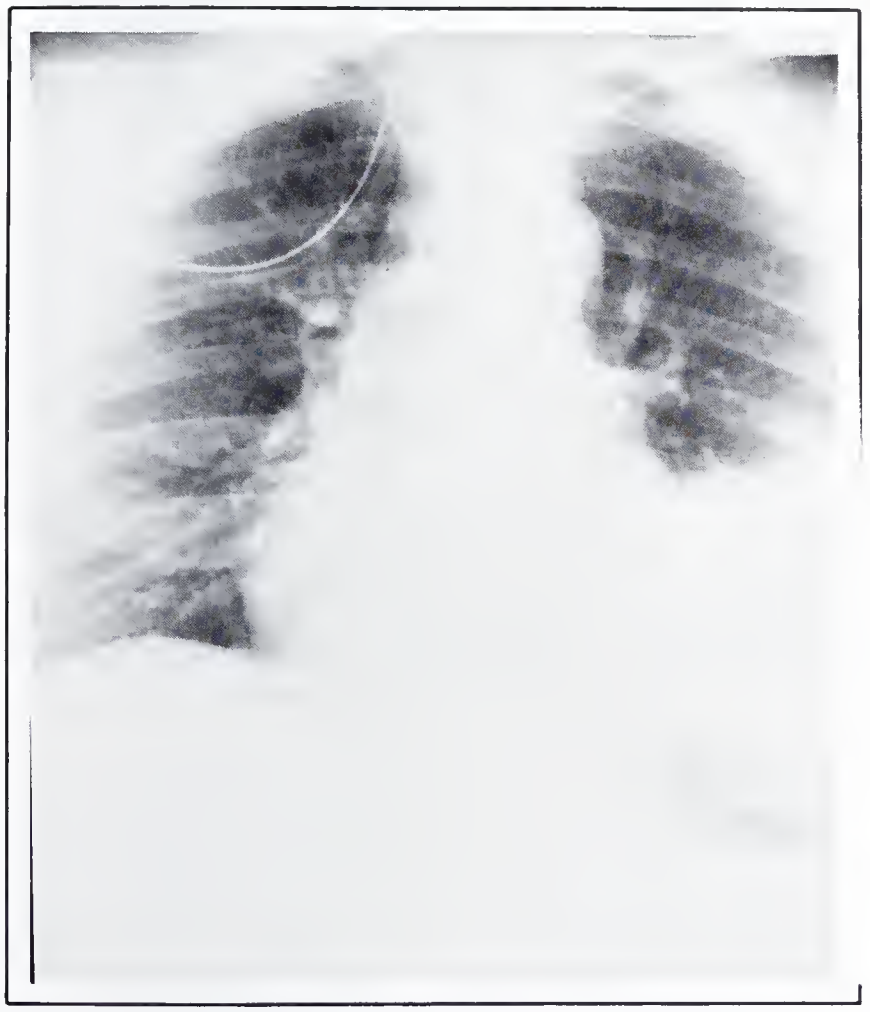


Fig. 1. PA view.

Fig. 2. Lateral view

What do these X-rays tell you?

A 49 year old woman presented with left shoulder tip pain of one hour duration. The pain developed while she was swimming and diving at a local municipal pool.

A. What finding(s) are demonstrated on the above chest films?

1. Left pleural effusion.
2. Changes consistent with COPD.
3. Left lower lobe pneumonia.
4. Multiple air densities in left hemithorax.
5. Obliteration of left hemidiaphragm.
6. Licorice overdose.

B. How would you confirm your diagnosis?

Answer on page 77.

FAMILY PRACTICE

The Investigation and Management of Infertility in Family Practice

James Vavougios, M.D.*, and Edward Domovitch, M.D., C.C.F.P.

The problem of infertility in Family Practice is not only an academic exercise in diagnosis and management but also a challenge in terms of educational and emotional ramifications. According to the American Fertility Society, "a marriage is considered barren or infertile when pregnancy has not occurred after a year without contraception." By this definition approximately 10% of couples find themselves confronted with this problem.[1,2] One must deal with the couple as a unit throughout the course of the investigation and treatment. The physician must be familiar with both male and female reproductive systems. A single physician is probably more effective in coordinating the workup and treatment of such a problem, and if properly tuned-in can minimize the emotional strain that is inevitable. Today's family practitioner is in the best position to serve this key role as coordinator. When his work-up requires specialist consultation this can be done with a gynaecologist, endocrinologist, urologist interested in infertility, or one of Toronto's infertility clinics such as those at the Mount Sinai Hospital and Toronto General Hospital.

The multiplicity of factors responsible for infertility necessitates the simultaneous investigation of both male and female partners. Approximately one third of cases show a male cause alone, one third of cases show a female cause alone, and one third of cases show a mixed cause.[3] Thus one should not stop when a single factor is found but should treat the factor and continue the investigation. In this review, both investigation and treatment will be combined.

Approximately one and one half hours is allotted for the first interview with the couple. A complete history is obtained and a complete physical done on both partners. A brief outline of human reproductive physiology is given and then the multiple investigations are planned. The complete workup should be finished in six to twelve months. A check list that can be filled in by the couple and physician is a good way of obtaining the relevant information. (See Tables 1 and 2.)

Table 1. Male History and Physical

General
Age
Number years married
Previous—marriage
—pregnancy
—investigations
Occupation

Past Health
—Gonorrhea, Syphillis, other STD
—Genital surgery
—Medication
—Radiation, chemotherapy
—Frequency, urgency, dysuria
—Cryptorchidism, hypospadias
—Mumps, orchitis
—Exposure to high temperatures
—Trauma to genitalia
—Sexual History
—puberty
—erection
—penetration, ejaculation
—use of lubricants
—Hormonal problems

Family History
—Chromosomal or congenital abnormalities
—infertility

General Functional Inquiry

Physical
—General appearance, body habitus
—Hair distribution, musculature
—Visual fields
—Blood pressure, heart rate
—Thyroid
—Breasts, galactorrhea
—Penis, meatus
—Testes (size, consistency, hernia varicocele)
—Prostate

Table 2. Female History and Physical

General
Age
Coital frequency and type
Previous—marriage
—pregnancy
—investigations
Occupation

*2nd Year Resident, Family Practice
Wellesley Hospital, Toronto, Ontario

Past Health
—Gonorrhea, Syphillis, P.I.D.
—Genital surgery
—Medication
—Radiation, chemotherapy
—Kidney or bladder problems
—Anorexia, obesity
—Sexual History
  —Puberty (age, onset, pattern)
  —Menses (frequency, onset, pain spotting)
  —Prior contraception.
—Hormonal problems

Family History
—Chromosomal or congenital abnormalities
—infertility

General Functional Inquiry

Physical
—General appearance, body habitus
—Hair distribution
—Visual fields
—Blood pressure, heart rate
—Thyroid
—Breast development, galactorrhea
—Pelvic
  —vulva, clitoris, urethra
  —vagina
  —uterus (symmetry, size position fixation, fibroids)
  —adnexae (masses, thickening, endometrosis)

Every physician dealing with an infertile couple must be ready to deal with the anxiety, anger, depression, and hostility that the couple is feeling. The couple may feel uncomfortable with neighbours who have children or they may feel threatened with the invasion into their sexual identity, activity and parenthood. Their failure to reproduce may send a young couple into argument after argument, gradually shattering their bond. An opportunity to vent such feelings is therapeutic. Explanations of tests and treatments help to dispel misinformation and ignorance. It can be pointed out that in approximately ninety per cent of cases a cause for the infertility will be found.[4] Counselling should be used not as a final method of resolving infertility problems when investigation and treatment have failed but rather as an initial treatment to alleviate an intense emotional turmoil that probably exists even from the onset of investigation.

As recently as twenty years ago, it was thought that emotional factors were responsible for twenty to forty per cent of infertility.[5] Today this value has been reduced to less than five per cent. In the past, infertile women were found to be more anxious, neurotic and dependent than fertile women.[7,8,9,10] In a study of men awaiting sentencing after raping and impregnating women, complete spermatogenic arrest was found on testicular biopsy in all cases.[6] Our conclusion derived from the literature review of this area, is that psychological problems among infertile couples exist, but there are few well controlled prospective studies that can show cause-effect relationship with infertility.[11] However, as was stated earlier, a couple can experience intense emotional turmoil during an infertility investigation that may affect their coital frequency and jeopardize a borderline fertile couple's chance of success.

The causes of infertility are multiple and a list is given for each partner in Tables 3 and 4 modified from Dr. J. Bain.[2]

Table 3. Causes of Male Infertility

Primary Testicular Failure:
Klinefelter's syndrome
Noonan's syndrome
Testicular agenesis
Sertoli-Cell only syndrome
Anomalies of the vas deferens or epididymis
Adult Seminiferous tubule failure:
  —Mumps orchitis
  —Bacterial orchitis
  —Gonorrhea, prostatitis
  —cryptorchidism
  —Myotonia dystrophica
  —Radiation, Chemotherapy
  —varicocele
  —Idiopathic

Secondary Testicular Failure:
Hypothalamus-pituitary
  —tumor
  —hypogonadotrophic
Adrenogenital syndrome
Adrenal tumor
Thyroid disfunction
Drugs (testosterone, estrogen)
Immunologic (autoantibodies)
Defective androgen action
  —complete testicular feminizatioon
  —incomplete testicular feminization
Mechanical
  —hypospadias
  —retrograde ejaculation
Psychological
  —impotence
  —anorgasmia

Table 4. Causes of Female Infertility

Hypothalamic-Pituitary
Functional amenorrhea
Tumors (micro or macroscopic)
Gonadotrophin insufficiency
Regular menses without ovulation

Thyroid

Adrenal
Cushings
Adrenogenital syndrome

Ovarian
Agenesis
Polycystic ovary syndrome
Insufficient corpus lutem
Tumor

Fallopian Tubes
Chronic inflammation or obstruction (endometriosis, tuberculosis, pelvic inflammatory disease.)
Adhesions post surgery
Congenital abnormalities

Uterus and Cervix
Infection (endometritis, mycoplasma)
Asherman's syndrome
Congenital abnormalities
Infantile uterus

Vagina
Imperforate hymen
Vaginismus
Lubricants

Chromosomal
Testicular feminization syndrome
Turner's syndrome

Immunological
Anti-sperm antibodies

Psychological
Abstinence
Contraception

Environmental
Drugs
Radiation
Chemotherapy

What can we tell a couple that is asking about their chances of conception? Even before any information is gathered from the couple, the physician knows from the results at several infertility clinics that successful pregnancy occurs in more than fifty per cent of couple seeking help.[6] Since the family physician is seeing couples earliest in the referral process, we hypothesize that the success rate would be even greater in the primary care setting. Prior pregnancies and maternal age under thirty are good prognostic indicators.[6] The pregnancy rate when a male partner has normal semen analysis is seventy-one per cent, and thirty-three per cent for semen that is severely defective. Furthermore, previous investigation itself does not seem to affect prognosis.[12]

After history and physical examination of the couple, it is recommended that ancillary tests be completed simultaneously. These tests are listed in Table 5. The tests as shown are organized in sequential order with the simplest and least invasive ones first. This order can be altered for individual cases if indicated.

Table 5. Tests of Infertility

Male Investigations	Female Investigations
Semen analysis (at least twice)	Basal body temperature chart
Hormonal studies —	Progesterone levels in luteal phase
LH	Post-coital testing
FSH	Hormonal studies —
T3RU, T4	—LH
Prolactin	—FSH
Cortisol	—T3RU, T4
17 ketosteroids	—Prolactin
Testosterone	—Cortisol
Immune studies	—17 ketosteroids
Buccal smear	—testosterone
Testicular biopsy	Mycoplasma culture of cervix
	Immune studies
	Endometrial biopsy
	Hysterosalpingogram
	Laparoscopy

Let us first deal with the investigation and treatment of the male partner since it is much simpler. The most important investigation in the male is the semen analysis. After two to three days of abstinence, a specimen is obtained by masturbation in a private room into a wide-mouthed glass jar. Rubber condoms may not be used and a special plastic pouch can be used to collect the sample if masturbation is not possible. At least two specimens three weeks apart must be collected as sperm counts can vary greatly. The normal values vary from lab to lab. Below are the normal values proposed by McCloud.[13]

Liquefaction	— within twenty minutes
Semen volume	— 2-5 ml.
Sperm concentration	— greater than twenty million per millilitre
Morphology	— greater than 60 per cent normal
Motility	— greater than 60 per cent moving with rapid progression

The presence of excessive white blood cells in the semen is abnormal and indicates an infection requiring treatment. A seminal fructose level is indicated in males with no sperm present as fructose will be absent in males with congenital aplasia of the epididymes and the vasa deferentia.

Once oligospermia (count less than twenty million) or azoospermia (total lack of sperm) is found, hormonal testing should be initiated, including: FSH, LH, prolactin, thyroid hormones, cortisol and testosterone. Figures 1 to 4 are taken from Swerdloff and Boyers[14] and will aid in the interpretation of these results.

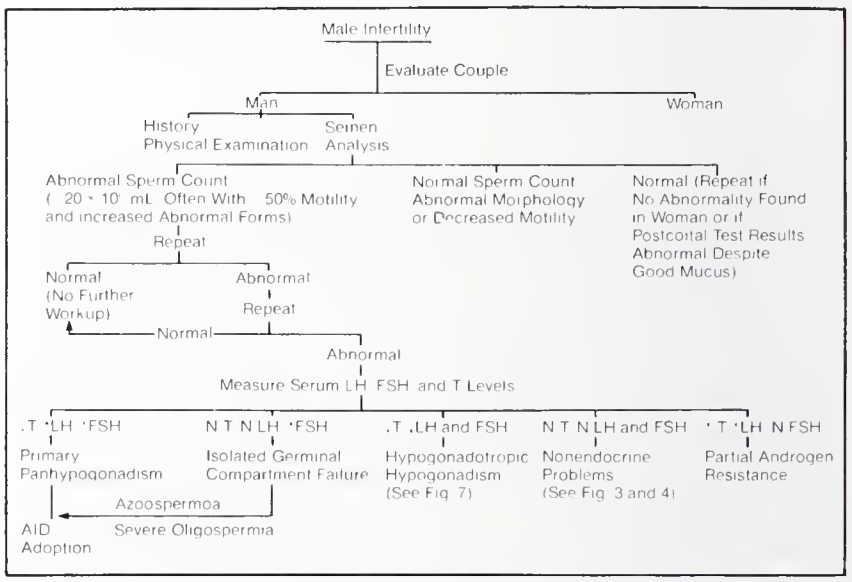


Figure 1. Diagnostic evaluation of potentially infertile man. LH indicates luteinizing hormone; FSH, follicle-stimulating hormone; T, testosterone; N, normal; AID, artifical insemination donor.

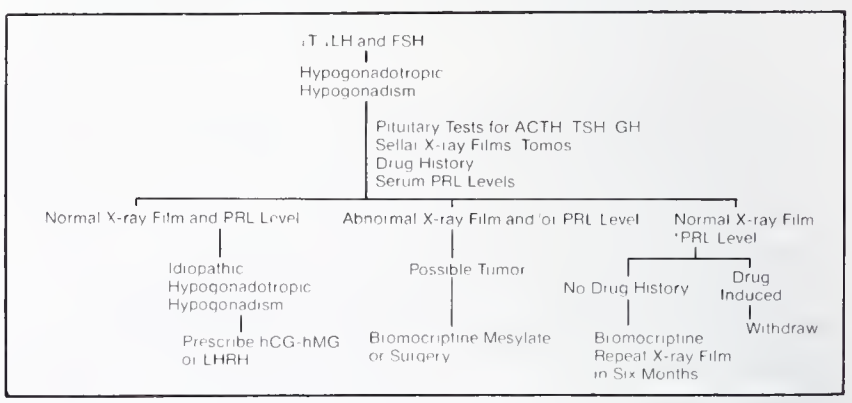


Fig. 2. Evaluation and treatment of patient with hypogonadotropic hypogonadism. T indicates testosterone; LH, luteinizing hormone; FSH, follicle-stimulating hormone; ACTH, adrenocorticotropic hormone; TSH, thyroid-stimulating hormone; GH, growth hormone; PRL, prolactin; hCG, human chorionic gonadotropin; hMG, menotropins (human menopausal gonadotropin); LHRH, gonadotropin releasing hormone (luteinizing hormone-releasing hormone).

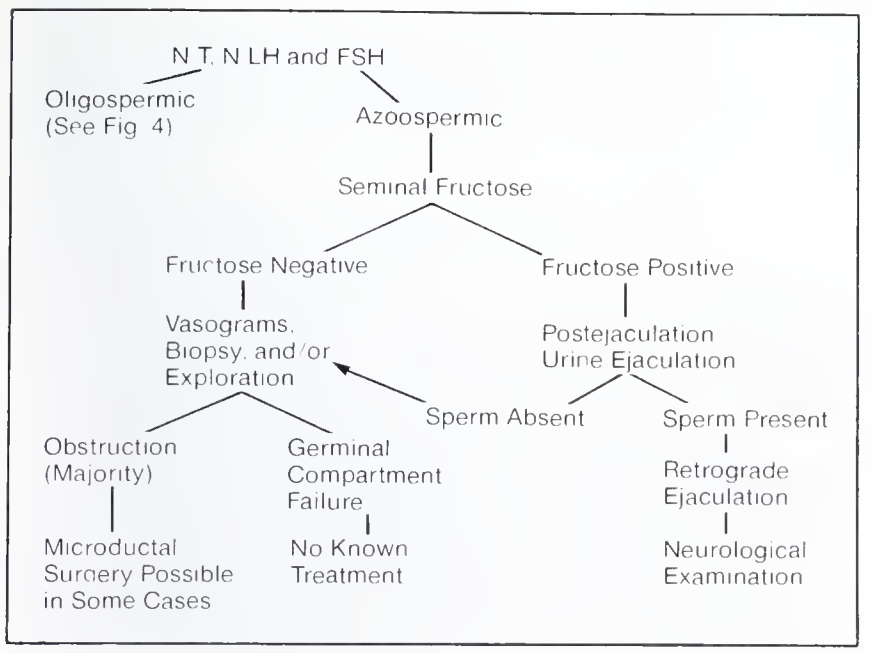


Fig. 3 Diagnostic evaluation of azoospermic man. N indicates normal; T, testosterone; LH, luteinizing hormone; FSH, follicle-stimulating hormone.

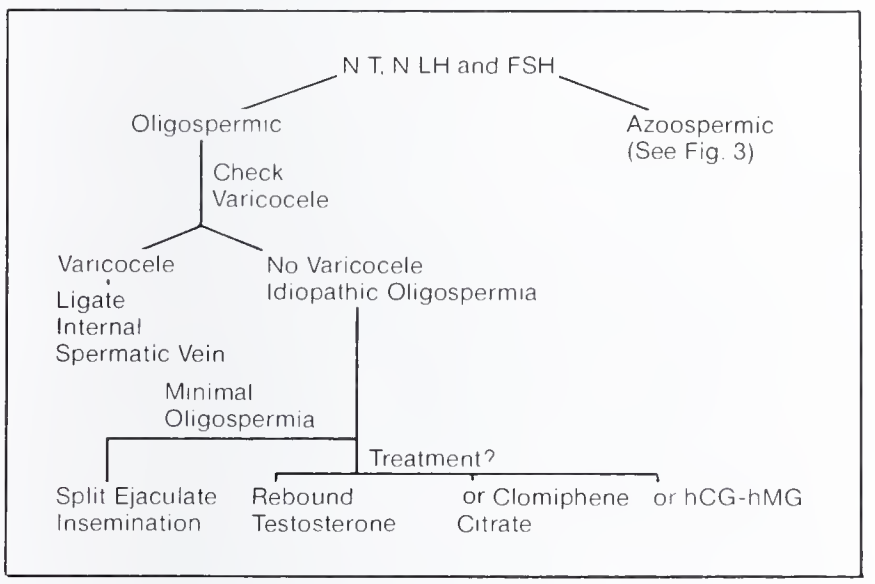


Fig. 4 Diagnostic evaluation of oligospermic man. N indicates normal; T, testosterone; LH, luteinizing hormone; FSH, follicle-stimulating hormone; hCG, human chorionic gonadotropin; hMG, menotropins (human menopausal gonadotropin).

When no cause for the oligospermia exists other than the finding of a varicocele, a ligation of the internal spermatic vein is recommended as significant improvement for semen quality has been noted for counts less than ten million.[15,16,17] The size of the varicocele is of no prognostic significance. In 1970, Dubin and Amelar found an 81% improvement in semen quality and 48% pregnancy rate in 111 males following ligation of the internal spermatic vein.[15]

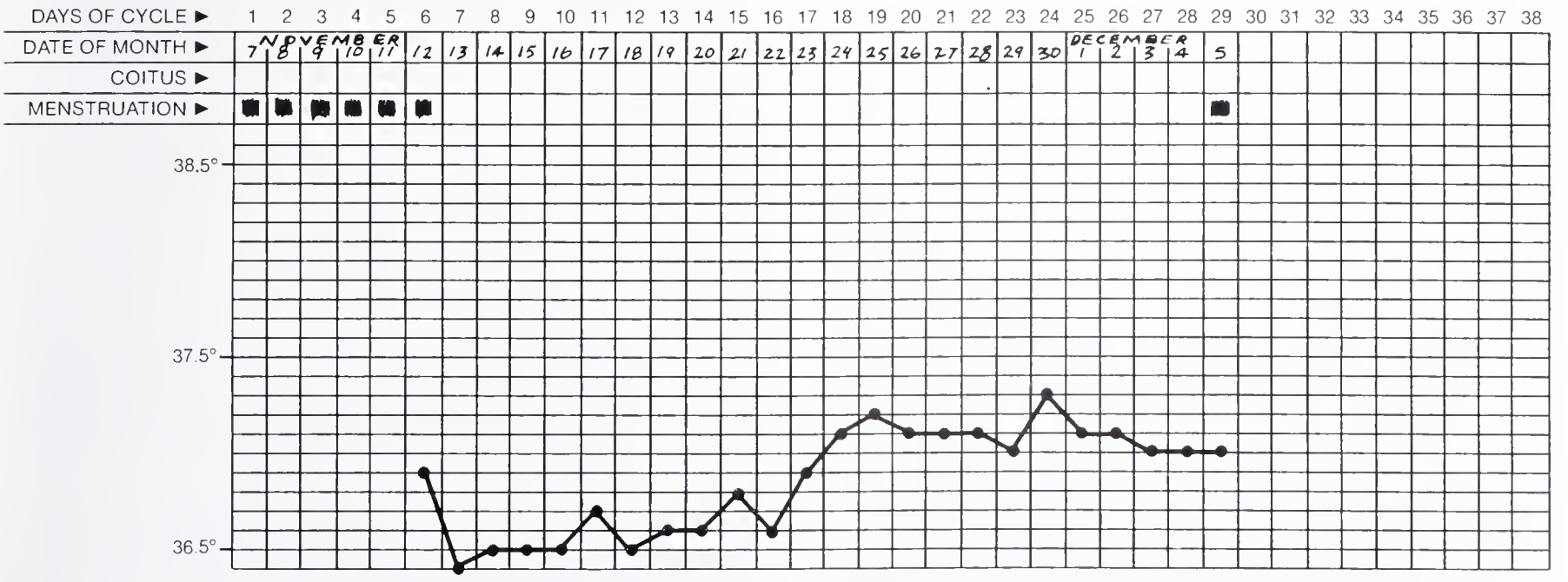
Sex chromatin determination in males with azoospermia can be used as a screen before testicular biopsy. However, a sex chromatin negative pattern does not rule out Klinefelter's syndrome.

Testicular biopsy is indicated in males with azoospermia, normal sized testes and a normal hormone profile. The presence of normal spermatogenesis on such a biopsy would indicate possibly a blockage between the epididymis and the vas deferens. Epididymovasostomy can be tried; however, this operation is successful in only 20% of patients and thus the yield of pregnancy is not great.

The various hormonal treatments for the improvement of semen of poor count or quality are expensive, require precise timing and are of questionable efficacy. Thus, these problems should be referred to the endocrinologist or infertility clinic. Treatments include clomiphene citrate, testosterone, human chorionic gonadotropin, human menopausal gonadotropin, and vitamin E.

The female workup is much more involved that that of the male. The basal body temperature chart (BBT) is the cornerstone of the investigation. It requires several months of charting and other investigations must be based on it. Thus it must be started early. The BBT is taken every morning at the same time using an oral thermometer. The temperature is taken for three minutes before rising. Fever, gastrointestinal upset, late partying, multiple awakenings at night, may all affect the BBT and should be marked on the chart. The charting is continued for at least three months. A typical BBT chart is shown in Figure 5.

Figure 5. A BBT chart.



The progesterone secreted in the second part of the cycle following ovulation causes a rise of the BBT to approximately 37.5°C. A biphasic chart with a sustained rise of 0.2° to 0.5°C for the second fifteen days is almost certain evidence of ovulation. Ovulation usually occurs on days thirteen to fifteen, just before the rise in temperature. The BBT is used to time ovulation for further testing and should not be used as a schedule for intercourse as it puts added stress on the couple to perform. Since the sperm are viable in the cervix for up to forty-eight hours, a coital frequency of two to three times a week affords adequate chance of fertilization.

The BBT chart is of diagnostic value in identifying corpus luteum phase defects, in which there is inadequate progesterone secretion to mature the endometrium for implantation of the fertilized ovum. There are basically two types of luteal defects. In one, there is a shortened life of the corpus luteum so that the rise in temperature only lasts five to twelve days. In the other, there may be a gradual rise in BBT plus or minus dips, but the length of the luteal phase is normal. It is important to note that the corpus luteum defect may only be diagnosed if it is found as a repeated pattern on the BBT since normal females may exhibit this pattern on an occasional cycle. It can only be definitely proven by endometrial biopsy.

The next step in confirming ovulation is the obtaining of a progesterone level in the luteal phase. A level of greater than 5 to 8 ng/ml is presumptive evidence of ovulation.[18] To assess function of the corpus luteum, two or more determinations in the luteal phase may be used. Because this test is less painful, it is recommended by some in lieu of endometrial biopsy.[19,20]

Endometrial biopsy is to be used only for the identification of the corpus luteum defect. For maximum information it is performed 1-2 days prior to menstruation. The anterior lip of the cervix is slowly grasped with a tenaculum, the uterus is sounded, and a biopsy is taken from high up in the uterus. This procedure is quite painful and the patient should be prewarned and encouraged to rest afterwards. This procedure can be done by the family practitioner in his office.

The post coital test is the next important step in the female investigation. The cervical mucus has been hypothesized to have three functions:[21]

(1) To facilitate passage of sperm in the fertile part of the ovulatory cycle and prevent passage at other times.

(2) To act as an obstacle to sperm which are not normally formed and motile.

(3) To provide a potential reservoir of sperm from which they may gain nutrition and wait for the follicle rupture.

This test must be carried out at a critical time when the mucus is thin, watery, acellular and receptive to the sperm. This occurs in the pre-ovulatory period (usually days 13 to 15). Following intercourse the couple presents to the physician's office. In the office a sample of mucus is aspirated from the vaginal fornix and a second one from the mid-cervical canal. Both samples are examined for the presence of spermatozoa at 100X and 400X magnification. The sperm in the vaginal sample are often non-motile because of the hostile environment presented by the vagina. In the mid-cervical sample there should be two to six motile healthy looking sperm per high-power field. The cervical mucus itself is scored. *Spinnbarkeit* is the ability of the mucus to be drawn out into a thin thread. Ferning is a fern-like pattern that results when the smeared mucus is air-dried on a slide. Table 6 gives a scoring scheme proposed by Moghissi.[22] The higher the score the better.

Table 6. Cervical Mucus Scoring.

Descriptive Factors	Scoring* 0	1	2	3
Amount	None	0.1 cc	0.2 cc	0.3 cc or greater
Spinnbarkeit	None	1-4 cm	5-8 cm	8 cm
Ferning	None	Atypical	2+	3+ to 4+
Viscosity	4+	3+	2+	1+
Cellularity (white blood cells per high power field)	> 10	6-10	1-5	Occasional

*Cervical mucus score greater than 10 is favorable, cervical mucus score less than five is hostile.
From Moghissi KS: The cervix in infertility. Clin Obstet Gynecol 22:32, 1979

The most common cause of an abnormal result is improper timing. When mucus is scant or absent, despite good timing with BBT, small doses of conjugated estrogen (Premarin 0.3-0.625 mg) daily for cycle days five to twelve may help. When numerous leukocytes are found in the mucus, systemic antibiotics may be used to treat the cervicitis. Cautery and cryosurgery should be avoided since these may damage the mucus glands. The absence of sperm from the posterior fornix may indicate anatomical, mechanical, or psychosexual problems in either partner. If sperm are present but dead, the cause may be unfavorable cervical mucus. Again the timing must be checked. However, there may be an immunological cause since the cervix is immunologically quite active.[23,24]

If there has been any evidence of an ovulatory disorder or hormonal imbalance, or if the investigations so far are negative, hormonal testing of the female partner is indicated. These tests are non-invasive and may yield a treatable entity. The hormones to be investigated are: LH, FSH, T3RU, T4, prolactin, cortisol, 17 ketosteroids, and testosterone.

In the polycystic ovary syndrome, there is an elevated serum LH with low or normal FSH. The treatment of choice for this condition is clomiphene citrate and only rarely should wedge resection be considered.[25] In one study done by Bates *et al.* on thirteen obese women with polycystic ovary syndrome, 77% of the women who lost greater than 15% of their body weight became pregnant without any further intervention[26]; hence weight loss should be considered.

The cause of unexplained secondary amenorrhea is prolactinoma in 20-30% of cases.[27] In another referred group of infertile women, 17% were found to have increased prolactin levels.[28] Of this group 3% had a prolactin secreting pituitary tumor. It is important also to note that most of the above women did not have galactorrhea. Bromocryptine (Parlodel) is approved for use in galactorrhea-amenorrhea associated with hyperprolactinemia and may reverse the infertility. Bromocryptine is contraindicated during pregnancy as its effects on the fetus are unknown. However, in all cases of increased prolactin levels a pituitary tumor must be ruled out.

Clomiphene citrate can be used for women who are not ovulating, ovulating very irregularly or those with a short luteal phase defect.[6] Clomiphene is a weak estrogen agonist that occupies the feedback receptors in the hypothalamus and stimulates LH and FSH release. This in turn leads to an accelerated production of estrogen from the ovary. The rising estrogens trigger an LH surge and ovulation occurs. The initial dose is usually 50 mg daily for five days starting on day five of the cycle. Success is judged using the BBT and progesterone levels. The dose is increased to 100 mg daily, then 150 mg and finally 200 mg daily for five days. Women with polycystic ovary syndrome are very sensitive to clomiphene and it should initially be given for only three days. Side effects include headache, visual problems, pelvic pain (ovarian cysts), and multiple pregnancies. If the patient ovulates, clomiphene is given for six consecutive months. During this period intercourse should occur five, seven and nine days following each course of clomiphene. Clomiphene has an adverse effect on the cervical mucus and Premarin 0.3 mg per day may have to be added as was discussed in the section on post coital tests.

The use of human menopausal gonadotropin, and human chorionic gonadotropin is more complicated and expensive and should be used by an infertility specialist.

Mycoplasmas or Ureaplasmas have been isolated from the genital organs for many years and have been implicated in diseases such as spontaneous abortions, non specific urethritis, and infertility. Because of the high incidence in asymptomatic controls there has not been any substantial evidence to their role in infertility.[29,30,31] Mycoplasmas are approximately the size of large viruses and lack a cell wall. In cases where there is a positive culture and no other cause for treatment is found, the couple should be treated. Treatment consists of doxycycline 200 mg on day five of the cycle and 100 mg on days six to thirteen. Pregnancy should not occur during the administration of the antibiotics. Both partners are to be treated and success can be determined by a repeat culture.

The role of immunological factors in infertility remains unclear. Human semen is an antigenic nightmare. Seminal plasma contains a vast array of antigens, many of which are common to other tissues. The spermatozoon has been shown to possess intrinsic antigens on the acrosome, midpiece and tail.[32] Many experts have differing opinions as to the most appropriate method of diagnosing immunologic causes of infertility. Anti-sperm antibodies have been found in the male plasma, female plasma, and cervical mucus. The treatment modes that have been tried are even more confusing: low-dose steroids, high-dose steroids, immunosuppresives, and condom therapy. Success is confounded by the lack of controls and poor selection of candidates. In a recent report, Shulman described a significant pregnancy rate of 44% in the wives of 111 men identified as having immunologic infertility and treated with methylprenisolone 96 mg per day for seven days.[33] This issue is still unresolved and steroids should not be used on a routine basis. A standard screening test for immunologic infertility still must be identified and further controlled studies of therapeutic success are needed.

An evaluation of the uterine and tubal factors has been left until the end as these are the most invasive tests and carry with them the highest morbidity. A history of pelvic inflammatory disease (P.I.D.), pelvic surgery or endometriosis would lead to an earlier investigation of the factors.[34] After a single episode of clinically apparent P.I.D. the incidence of infertility is 21%.[35] Thus, early diagnosis and aggressive treatment of P.I.D. is imperative for the primary care physician.

Hysterosalpingography (HSG) should be done if the infertility workup is negative after four months of investigation. HSG involves injection of dye through the cervix into the uterus, the tubes, and into the peritoneum. Thus, it outlines problems in both the uterus and tubes. It is complementary to laparoscopy since 17% of abnormalities found by HSG cannot be found by laparoscopy.[36] There is often a false positive obstruction on the HSG due to spasm at the utero-tubal junction. The HSG is done by a gynecologist. It can be painful so the patient should be warned.

Laparoscopy is the final step in our investigation of the couple for which no cause of infertility has been identified. It is indicated earlier in the investigation if an obstructive lesion of the fallopian tubes is suspected. It can be used to differentiate between polycystic ovary syndrome and masculinizing ovarian tumors. The incidence of unsuspected lesions, pelvic adhesions or endometriosis has been reported as high as 60% on laparoscopy.[6,38] It is recommended that the laparoscopist be skilled in microsurgery to avoid repeat examinations. Possible complications of this procedure are bleeding and perforation of viscera, but are uncommon in skilled hands.

Today, tuboplasty, especially microsurgical tuboplasty is a long operation lasting perhaps 4-6 hours. This is a major undertaking and despite all the new advances in atraumatic technique, nonreactive sutures, antibiotics and anti-inflammatory agents, a successful pregnancy rate greater than 25% is unlikely.[6] Unquestionably, such surgery should be referred to an infertility clinic where this type of surgery is at least a weekly occurrence and the success rate is theoretically higher. Gomel, in 1980, reported a 64% pregnancy rate for microsurgical reconstruction of tubes following tubal ligation.[39] Tubal ligations are therefore not recommended in patients who are at all equivocal about their desire for future pregnancies.

Endometriosis is definitely associated with infertility. There are many theories as to the cause of endometriosis which will not be discussed here. Forty per cent of patients with endometriosis are infertile.[40] With early stage lesions a trial of danazol has proven efficacious for severe pain. In one study, it was found that the use of danazol for 6 months for minimal endometriosis only delayed pregnancy and had no beneficial effect on pregnancy following the drug's cessation.[41] For more advanced stages, where there are adhesions or ovarian cysts, only surgery is of use. With surgery, there is a 75% pregnancy rate for mild cases, 50% rate for moderate cases, and 33% rate for severe cases.[6]

If the aforementioned investigation and treatments have been completed there are still three things to consider:

(1) Adoption
(2) Artifical insemination
(3) *In vitro* fertilization

Adoption is quite a viable alternative for many couples and should be discussed early in the investigation, if indicated, since waiting lists are long.

Artifical insemination by husband or donor has been used for many years. Insemination with the husband's semen is tried if there are mechanical or anatomical problems, or if there is oligospermia with a relatively better count in the first part of the ejaculate. Donor inseminations (AID) is accomplished with frozen semen imported from a large centre (like New York City) or with fresh semen obtained from university students. Anonymity of the donor is imperative. Couples should be advised that success is not guaranteed but can be reassured that there is no increased risk of fetal anomalies. They are given adequate time to consider their options and if agreeable a consent form is then signed. This procedure is usually performed by a gynecologist. Half a millilitre of semen is placed into the mid-cervical canal on alternate days (2-3 times) in the pre-ovulatory period. A six month trial is usually given. This is an excellent form of treatment in the case of azoospermia. The donor's sperm may be matched for race, height, hair colour, eye colour, and build of the husband.

In vitro fertilization (IVF) is the newest method of treating infertility. Its possible applications are enormous. The first successful pregnancies were documented in Norfolk, England. Using very strict quality control they were able to ensure a high yield of oocytes and subsequent pregnancies.[42] With their method in 1981, they were able to obtain a 13% pregnancy rate where a single conceptus was implanted, 31% pregnancy rate for two conceptuses and 50% pregnancy rate where three conceptuses were implanted simultaneously. Of interest also are the successful attempts of other investigators to transplant donated eggs to sterile women.[43] At Toronto East General Hospital, a team has been successful in their attempts at IVF and are now attending to a twin pregnancy.

Infertility remains a common and treatable problem in our society. The family physician should take on a greater role in the initial investigations and should remain an integral part of subsequent management, especially in dealing with its psychosocial aspects, if consultation with specialists is required.□

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OBSTETRICS AND GYNECOLOGY

In Vitro Fertilization (IVF)

*F. Khamsi, S. Batarseh, M. Kroach, P. Phillips, G. Woo, J. Dorrington, P. Leung, and M. Sutton

This technique has been used mainly for women who have irreversible blockage of the fallopian tubes, because of previous pelvic inflammatory disease or surgery for bilateral ectopic pregnancies. Originally, the timing of ovulation was assessed by serial estrogen and luteinizing hormone (LH) estimations and, more recently, by observation of the ovaries with diagnostic ultrasound. Over-stimulation of the ovaries to produce several mature eggs is achieved by serial use of clomid and/or human menopausal gonadotrophin (HMG) followed by one injection of human chorionic gonadotrophin (HCG) which causes ovulation. Just before ovulation, a laparoscope is introduced into the woman's abdomen under general anesthesia and two or more follicles are aspirated. These are incubated *in vitro* with the husband's sperm, and in most cases, fertilization takes place. The fertilized egg undergoes division to the two-to-four-cell stage and at this time the embryo is transferred back into the woman's uterus.

1. Introduction

a) Definition of IVF: This technique entails the removal of an egg from a mature follicle of the ovary a short time before ovulation and fertilization of the egg by the addition of spermatozoa in a controlled environment with subsequent development of a two to four-cell embryo within 48 hours which is transferred to the woman's uterus by a cannula inserted through the cervix.

b) History: This technique was originally reported by Drs. Steptoe and Edwards from the University of Cambridge, England in 1978.[1] Two groups from Australia also have contributed greatly to the further development of the technique and introduction of cryopreservation of the embryo.[2,3] In the United States, the husband and wife team of Jones[4] are responsible for the introduction of these techniques in North America at the University of Eastern Virginia Medical School.[3] Since that time other groups of clinicians and basic scientists throughout the world have utilized this technique and have introduced various modifications.

2. Patient Selection

a) Assessment of the Male: The male is assessed carefully for physical and mental health and a sperm count is performed. In most cases the male partner has a normal sperm count, but in some programs, males with mild sperm disorders of motility or number have been accepted with some success. In a relatively small percentage of the cases, *in vitro* fertilization has been used entirely because of male sperm disorders.

b) Cause of Infertility of the Female: The technique of IVF is used primarily for women who have obstruction of their fallopian tubes which can not successfully be repaired surgically. Many patients have had bilateral tubal removal for a variety of causes such as bilateral ectopic pregnancies, pelvic inflammatory disorder, or endometriosis. The technique of IVF has also been utilized for infertile couples of unknown causes where all the tests of the male and the female have been normal.

c) Age of the Female: Fertility in women gradually decreases with progression of age. For this reason, in most centres, they have confined their attention to women of 35 years or younger.

d) Absence of Other Physical or Mental Problems: *In vitro* fertilization is a rather complicated program and calls for considerable degree of patience and understanding, requiring both the physical and mental well-being of the woman. For this reason most programs favour couples who are in good physical and mental health

3. Observation of the Patients during their Menstrual Cycle with Stimulation of the Ovaries

a) The Use of Estrogen for Monitoring: It is now recognized that the serum estradiol value gradually rises during the menstrual cyle and reaches its peak value approximately 36 hours before ovulation. It declines sharply with a subsequent lesser rise towards the end of the menstrual cycle. Therefore serial estrogen determinations are used to monitor the women during the menstrual cycle to assess the maturity of the growing follicle(s). However, two or more immature follicles may produce the same amount of estrogen as one mature follicle, and therefore a technique that can actually visualize the follicle(s) combined with estradiol determinations provides a more accurate assessment of follicular development.

b) The Use of Diagnostic Ultrasound for Monitoring: With this method it is possible to see the follicles as small as 2 mm on day 7 of the menstrual cycle and subsequently observe the growth over the ensuing days. Figure 1 shows how the

*"Life" Programme

Gynecology
Dr. S. Batarseh, M.D., F.R.C.S.(C)
Dr. M. Kroach, M.D., F.R.C.S.(C)
Dr. P. Phillips, M.D., F.R.C.S.(C)
Dr. G. Woo, M.D., F.R.C.S.(C)

Endocrinology
Dr. F. Khamsi, M.B., F.R.C.P.(C)
Laboratory
Dr. J. Dorrington, Ph.D.
Dr. P. Leung, M.D., F.R.C.S.(C)
Urology
Dr. M. Sutton, M.D., F.R.C.S.(C)

growth of follicles can be well visualized with serial ultrasound. At day 7 of the menstrual cycle, the follicles were quite small measuring only 2-4 mm. These subsequently grew to mature size when the average diameter of the follicle was approximately 1.8 cm.

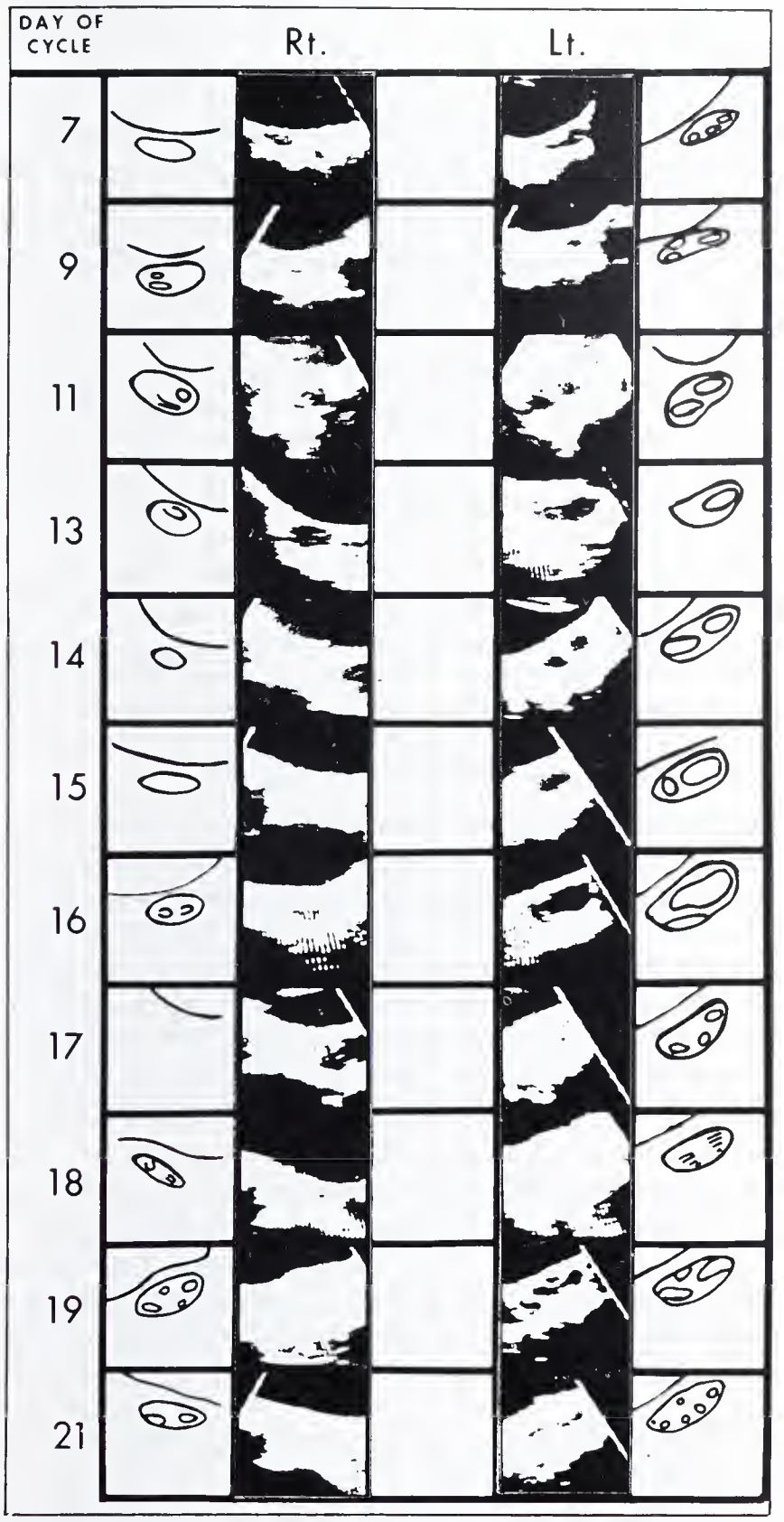

Fig. 1 Daily ultrasound examination during a normal menstrual cycle showing the growth of the dominant follicle in the left side reaching the maximum size at day 16th of the cycle. The follicles appear as blank areas.

c) The Use of Clomiphene for Stimulation of Ovulation: Clomiphene may be used alone to develop more than one follicle. At a dose of 150 mg/day for several days at the beginning of the cycle it is possible to obtain an average of 2.4 mature follicles. In most centres Clomiphene is used in the first few days of the cycle (day 3 to day 7) to encourage the *development* of several follicles. Subsequently, human menopausal gonadotrophic (HMG) is used for eventual maturation of five to ten follicles.

d) The Use of HMG for Stimulation of Ovulation: Several centres have and are using HMG only for stimulation of ovulation. HMG has an effect quite similar to human follicle stimulating hormone (FSH) of the anterior pituitary gland. The aim is to produce similar stimulation but at a greater dosage so that many follicles ripen.

e) Combined Use of Clomiphene and HMG: The combined use of Clomiphene and HMG results in the development of several follicles simultaneously whereas HMG by itself may ripen follicles at different ages. At present, most centres use Clomiphene 100 mg, daily from day 3 to day 7 inclusively and HMG in the form of Pergonal 150 IU (2 amps)/day from day 7 until two of the largest follicles have reached a size with the longest diameter of 1.8 cm.

f) Use of HCG for Induction of Ovulation: In the normal human menstrual cycle, the growth of follicles is stimulated with FSH (pharmacologically by HMG) and then there is a surge of LH from the anterior pituitary gland which results in ovulation. The LH surge is produced pharmacologically by injection of human chorionic gonadotrophin (HCG) which is obtained from urine of pregnant women. An injection of 5000 Ug of HCG is given 36-60 hours after the last dose of HMG. This timing is judged by doing serial estrogens and administering the HCG when the estrogen values have reached a plateau.

g) Luteinizing Hormone (LH) Monitoring: In the normal menstrual cycle, ovulation is preceded by a surge of LH secreted by the anterior pituitary gland. From the time the last dose of HMG is given to the time the only dose of HCG is administered, serial blood values of LH are taken. Usually the LH values remain low, but should there be a surge of LH in the blood, laparoscopy is performed 36 hours after the onset of the LH surge or the cycle of treatment is interrupted and the patient restarted in her next menstrual cycle. This is a relatively uncommon occurrence because with the regimen discussed above, the LH surge does not occur in most patients and their ovulation is induced by the injection of HCG.

h) The Time from Injection of HCG to Laparoscopy or Ovum Retrieval: Investigative work has shown that ovulation usually takes place 36-40 hours after administration of HCG in the regimens discussed above. Therefore, the timing of laparoscopy and ovum retrieval is critical and this usually is done 30-36 hours after the injection of HCG. If left too late, again ovulation may take place and the ovaries would lack mature follicles for retrieval. It is to be noted that, at present, discharged ova cannot be retrieved from the abdominal cavity.

4. Ovum Retrieval

a) The Technique of Laparoscopy: Laparoscopy is a commonly used technique in gynecology and the purpose is to visualize the pelvic organs without a complete surgical operation. For laparoscopy, the patient is given a general anesthetic and then a small incision of approximately 1 cm is made close to the umbilicus. The laparoscope is passed through this hole and with the fibroptic technique, the abdominal and pelvic organs can be seen.

b) The Specific Needles Used for Puncture of the Follicles: Specific needles have been designed to be introduced through a very small hole in the lower abdomen into the pelvis. The

path of this needle is watched through the laparoscope, so that each of the large follicles can be punctured.

Identification of the Ovaries and Follicles: Prior to admission of the patient to the *in vitro* fertilization program, they must undergo an investigative laparoscopy. The purpose is to see if the ovaries can be seen through a laparoscope and to assess how much of each ovary can be visualized. This is very important for the laparoscopy and ovum retrieval during the IVF cycle. If the ovary is completely covered by adhesions and fibrous tissue, then the operator cannot identify this organ and it is not possible to retrieve the ova. Patients with such problems may first have their ovaries freed during the investigative laparoscopy.

d) Puncture of the Follicles and Removal of the Fluid and Measurement of the Quantity: The special needle is introduced into each large follicle with direct visualization through the laparoscope and the content of the follicle is aspirated into a culture tube. The procedure is repeated until the large follicles are emptied. This technique appears to be fairly innocuous, although there may be a small amount of bleeding into a follicle with subsequent cyst formation as noted by follow-up ultrasound examination. It hs been reasonably well demonstrated that ovaries are not damaged by this.

e) Examination of the Fluid for the Presence of Ovum: The surgeon passes each of the tubes containing the aspirated follicle to the technologist who measures the volume and subsequently expels the content of the tube into a dish. Using a dissecting microscope, it is determined if the fluid contains an ovum and this is quickly transferred to a culture medium and placed in an incubator. The procedure is repeated for each tube.

f) Length of Stay in Hospital: In some centres, the whole of the IVF Program is done as Out-Patient with admission to hospital for 6-8 hours for laparoscopy. In other centres, the patient is admitted to hospital from the time of last HMG injection and is kept in up to the time of embryo implantation. The advantage of hospitalization for this period is convenience to the patient and ability to monitor the LH value more carefully from the time of HMG injection to administration of HCG. However, it is anticipated that in future most centres will adopt an Out-Patient technique due to the considerable cost of hospitalizations.

5. Laboratory Fertilization of the Ovum

a) Specific Attention to Glassware and Medium Preparations: The human ovum is an exceptionally delicate structure and meticulous attention has to be paid to cleanliness of the glassware. Generally, plastic containers are avoided due to contamination with chemicals that may be harmful to the ovum. Each glassware item is soaked in detergent and subsequently washed and re-washed numerous times to remove all foreign materials from it. The same meticulous attention must be paid in the preparation of tissue culture medium, which is used to contain the ovum and the embryo. The tissue culture medium is similar to that used in other human tissue culture preparations. Serum from human cord blood and from the women's blood are also used as medium to nourish the ovum and embryo.

b) Other Equipment Including Incubator, pH meter and Osmometer: The incubator is a very important item in IVF laboratories and generally two are used so that in the event of breakdown, valuable material is not lost. At any one time, the incubator may contain the ovum or embryo from several patients. It is advisable to have constant monitoring of the environment of the incubator and an alarm system that will alert the physicians to any detrimental changes in the environment of the incubator. One centre has the incubator alarm connected to the neighbouring ward's nursing station which is manned around the clock. In essence, the human tissues that are placed in these incubators are the result of extensive preparation and manipulation of the woman and deserve very careful attention to avoid any detrimental exposure to hostile surroundings. It is also very important to keep a close monitor of the pH of all media used since human tissue can only survive in very narrow pH range. Meticulous attention will also have to be paid to the osmotic pressure of the medium. It is to be noted that only a small amount of medium is used in each of the preparations and evaporation will result in an increase in osmotic pressure. Therefore, all the dishes have an outside well where water is kept to maintain the environment high in humidity.

c) Preparation of Sperm: The specimen is centrifuged for 5 minutes and washed with medium one-to-two times. Only those active sperm capable of swimming up into the supernatant from the resuspended pellet on the bottom of the tube are used. A count is done initially and in the final concentration so a fairly specific number of sperm can be used for insemination of the pre-incubated eggs.

d) Introduction of the Sperm to the Egg: Normally, several million sperm enter the vagina and some eventually manage to pass through the cervix and meet the ovum in the fallopian tube. However, with the sperm preparation indicated above, only 50,000 to 100,000 sperm are required to achieve fertilization. It is for this reason that the above technique of sperm preparation has been useful in the case of some of the male infertility problems with low sperm count or low motility. A sperm sample is introduced into each of the dishes containing an ovum.

e) Subsequent Observation of the Egg for Fertilization: This process has been elegantly documented with the use of time phase cinematography. Generally, only one sperm penetrates the ovum, but in the laboratory more than one sperm has been seen to penetrate a single ovum. Such polyspermic eggs are not reintroduced back into the women's uterus.

f) Cell Division: The fertilized ovum is observed over the ensuing hours to go into the two-cell and four-cell stage.

g) Timing of Embryo Transfer: This is done approximately 48 hours after the ovum retrieval. If the embryo is allowed to divide much beyond the eight-cell stage, the success of implantation may be reduced.

6. Embryo Implantation

a) Preparation of the Patient: This procedure is usually done in an Operating Room where there is reasonable degree of sterility. The patient is fully conscious and is placed in the lithotomy position. The whole procedure takes less than 30 minutes.

b) Aspiration of Embryo into Tubing: A thin flexible tube is connected to the end of a very small syringe. The fertilized

egg at the two or four-cell stage is aspirated in a very small amount of fluid into the tubing. It has been noted that the best success is achieved by transfer of three embryos. Transfer of less or more embryos reduces the change of achievement of pregnancy.

c) Introduction of the Tube into the Uterus: This fine tubing is then guided to a previously determined length into the uterus. It has been noted that with all the precautions and finesse of the technique, the lining of the uterus is still mildly damaged and there is a small amount of bleeding as a result of introduction of the catheter into the uterus. This procedure is not painful to the patient, but may be mildly uncomfortable.

d) Injection of the Embryos into the Uterus: The embryos are in a volume of 20-40 u of fluid. Any larger amount of fluid will result in its draining through the cervix and loss of the embryo from the uterus. Sterile technique is observed throughout all the procedures and therefore uterine infection has not been a problem. The tube is removed and is observed under the microscope to ensure that all the embryos were transferred. Occasionally, if an embryo remains attached to the side of the catheter, it is put back into the medium and aspirated and reinjected into the patient. In some centres, the patient is kept in the hospital for a short period of time and in other centres, she is sent home and advised not to be too active for a few days.

Achievement of Pregnancy

a) Variable Success at Different Centres: The best results achieved are only at a few centres in the world not exceeding five in number where approximately 20-25% pregnancy and approximately 10% live birth is achieved (per trial). There are several other centres who have success rates of 1-10%.

b) Multiple Births: In most centres, approximately three embryos are transferred into the uterus. However, achievement of even a single pregnancy is variable ranging from 0-24% in different centres. Multiple births including twins, triplets and quadruplets have occurred, but it is an uncommon occurrence and has not been a major problem in this program.

c) Fetal Abnormalities: Occurrence of fetal abnormalities has been a particular concern in this program. However, the international experience has shown that there is no demonstrable increase in fetal abnormalities in children born with this program as compared to the rest of the population.

8. Direction of Future Research

a) Ovum Retrieval under Ultrasound Guidance without Laparoscopy: A group of investigators from Denmark have pioneered the use of diagnostic ultrasound for aspiration of various abdominal and pelvic organs in the last ten years. Recently, they have applied the same technique to retrieval of ova from follicles in the ovaries. The patient is either conscious or has received mild sedation. Alternatively, the patient may be placed under general anesthesia. With the usual technique of diagnostic ultrasonography, the ovary and the mature follicle are shown. Then a relatively fine needle of approximately 2 mm outer diameter is introduced through the skin and its passage is observed with the ultrasound transducer. The needle will go through skin, muscle, wall of the urinary bladder entering the bladder and then going out of the wall of the urinary bladder and into the follicle in the ovary. The needle has an inner core and an outer sheath. The inner core is removed and a syringe is applied and the contents of the follicle are aspirated. This technique has proven to be quite safe in the hands of the Danish and more recently, a Swedish group. They did cystoscopy after the procedure to assess damage to the urinary bladder and no damage was found. A very small percentage of the patients had minor transient hematuria. There was no intra-abdominal bleeding. The needles used have been quite fine and there has been a question of possible damage to the ovum following aspiration through a fine needle. Through this technique there has been ovum retrieval slightly lower than what is achieved by laparoscopy. The percentage of fertilization of ova has been similar to what has been obtained in the cases where laparoscopy was used. However, there has been only one report of pregnancy using this technique. The technique of ovum retrieval without laparoscopy is a very attractive possiblity as this means that IVF may become an office procedure. However, the question that has to be answered is whether the use of narrow bore needles may damage the ovum, and what are the feasibilities of using a needle with larger bore than 2 mm for this purpose.

b) Technique of Freezing Embryos: In 1983, one of the groups from Australia reported that they have been freezing embryos and on at least one occasion, using a frozen embryo, they achieved a pregnancy. The ability to be able to freeze embryos has several advantages. When more than three embryos are produced, three of these may be transferred to the woman's uterus, and the rest may be frozen.

In the next cycle, the frozen embryos may be defrosted and placed back in the woman's uterus at the appropriate time. In this way, a second general anesthetic and laparoscopy are not required. The ability to freeze an embryo brings up a number of legal and ethical questions that will have to be tackled over the next few years. However, centres that are freezing embryos have introduced some guidelines so that it is reasonably clear at the onset what will happen to an individual embryo. One of the centres about to introduce this technique in North America has the following guidelines: an embryo is to be used either for transfer back into the woman's uterus or be given to another family with the consent of the husband and wife or be used for short-term medical research of a total of two week's duration.

c) Surrogate Uterus: Patients who have lost their uterus for one reason or another and have normally functioning ovaries and a healthy husband, may ask for a surrogate uterus. The patient's ovum is removed with the technique of IVF and fertilized *in vitro*. Subsequently, it is placed in the uterus and the fetus develops in this environment.

4. Conclusion

As can be appreciated in the above discussion, *in vitro* fertilization has brought hope to many infertile couples. However, the program requires cooperation by people from many disciplines: gynecology, endocrinology, tissue culture, and radioimmunoassay. Also a large amount of sophisticated equipment and specialized facilities are required consisting of an

operating room, diagnostic ultrasound equipment with high resolution in real time, a complete tissue culture laboratory and a radioimmunoassay laboratory.□

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Explanation *of the* Tables.

Tab. XXXVI.

Divers Views of the external, middle, and internal Compages of the Fibres of the Heart.

Fig. I.

The fore part of the Heart, next the Sternum.

A The inferiour Trunk of the *Vena Cava.*
B The *Arteria Pulmonalis.*
C, C, C The *Vena Pulmonalis,* with its Branches tied up.
D The *Arteria Magna.*
a The *Ligamentum Arteriosum,* between the Pulmonick Artery and the *Aorta.*
b The Trunk of the *Arteria Coronalis.*
E The right Auricle diſtended, to ſhew the Series of its Muſcular Fibres.
F The Left Auricle.
G The oblique deſcending Progreſs of the Muſcular Fibres of the right Ventricle of the Heart.
H The oblique aſcending Progreſs of the carnous Fibres of the left Ventricle.
I I The tendinous Union of both theſe on the *Septum* of the Heart.

Fig. II.

The back part of the Heart, next the Vertebræ.

A The lower, or aſcending, Trunk of the *Vena Cava.*
a a The circular Fibres appearing on its inſide.
B A Portion of the upper, or deſcending, Trunk of the *Cava.*
b The *Vena Coronaria.*
C The *Vena Azygos* tied up, where it diſcharges it ſelf into the *Cava.*
D D The right Auricle, repreſenting the various Diſpoſition of its Fibres.
F Part of the Root of the left Auricle *in Situ.*
G The Muſcular Fibres on the bulbous Trunk of the *Vena Pulmonalis.*
E E Two of its Ramifications from the Lungs, tied up.
H The Fibres of the right Ventricle.
I Thoſe of the left Ventricle.
K K Their tendinous Union, on the *Septum Cordis.*
L The *Foramen Ovale,* ſomewhat appearing.

W. Cowper, *Myotoma reformata,* R. Knaplock, London, 1724.

ETHICS

IVF-ER/T and The Ethical Physician: Six Questions

Abbyann Lynch, Ph.D.*

That use of *in vitro* fertilization — embryo implantation techniques is of more than technical, scientific and medical import seems apparent. Indeed, the "social, ethical and legal implications of recent and potential developments in medicine and science related to human fertilization and embryology"[1] are already under widespread formal and informal consideration by many public, private and professional groups. In Canada, for example, the Attorney General has asked the Ontario Law Reform Commission to make recommendations in this area. In Australia, the "Waller Committee" is still in session. In the U.S., the activities of the Ethics Advisory Board and the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research are well-known in this regard. Here in Britain, the report of the Government Inquiry into Human Fertilisation and Embryology under the chairmanship of Mrs. Mary Warnock (an Oxford professor of philosophy) is expected within the year.

Physicians, whether researchers, clinicians or educators, could be expected to evince interest in these more general implications of the use of *in vitro* fertilization — embryo implantation techiques (IVF-ER/T), and this for several reasons. With all other citizens, physicians will share the cost of making these techniques publicly available even as they will share in the public costs of support for relevant research proposed. Physicians, too, will live in that larger society in which availability of these procedures may be expected to have some general impact on family structure, for example, on intersexual relationships, on the role of women as childbearers, on the present limits of research using human subjects. Physicians may be among those who participate in these procedures, thus claiming interest other than professional in the consensual or confidential aspects of the use of these procedures. Beyond such sharing in public concerns around these matters (and thus in public concern for appropriate public utilization and regulation of such technologies), however, physicians will have an interest here as primary dispensers of these therapeutic and diagnostic measures. If not as direct dispensers, physicians will be asked for advice about these measures. Individually or collectively, whether reflectively or by reflex, physicians will (inevitably) adopt a viewpoint about these issues. The questions remain: will the viewpoint be adopted knowledgeably or by default; what will that viewpoint be?

As preface, this essay is addressed to the reader whose response to such questions reflects a bias towards knowledge. It is born of the conviction that query prepares response, that knowledge in these matters is an ongoing personal responsibility. If it be granted that knowledge begins in self-examination, use of available professionally-prepared "ethical statements" should be helpful. (In any case, when addressing readers of the *Medical Journal*, reference to the medical literature is much the safest course and rarely contraindicated). With one exception, the four "medical" papers chosen as basis for discussion here reflect the opinions of the principal professional groups in one locality: comparison and sharp questioning of their content is thus possible and perhaps profitable. In any event, the exercise should be less traumatic than similar inquiry based on (the almost non-existent) statements of the domestic variety. Finally, since the matters for investigation are arguably not "medical" merely, indulgence in the introduction of (a few) resources not "medical" merely is sought.

* Associate Professor, Philosophy, U of Toronto (St. Michael's College)
Member of planning group, Medical Humanities, U of T Medical Faculty
Hospital Appointment: Obstetrics and Gynaecology, St. Michael's Hospital

Question One

What is the subject, i.e. what is in vitro *fertilization — embryo implantation?*

"*In vitro* fertilization — embryo implantation" is the title for a series of techniques which involves:

1. removal from a woman by a surgical operation, usually a laparoscopy, of one or more ova at the phase of impending bursting of the Graafian follicle. The follicle may have reached this stage naturally, but sometimes procedures inducing ovulation or superovulation are instituted and the latter may lead to more than one "ripe" ovum being available for harvesting.
2. maintenance of each ovum in an artificial environment with a short bath *in vitro* (laboratory glassware) in male sperm.
3. placement of the embryo within the uterus of the donor mother or of another female (if fertilization has occurred and early cell divisions of the embryo have begun), or use of the embryo for research purposes.
4. implantation may take place and development of the embryo may proceed to full term and to a live birth, if the embryo has been replaced in a uterus (via the cervix).

At present, in relation to *in vitro* fertilization (IVF), the term "embryo replacement" (ER) is used when the embryo is returned to the donor mother and "embryo transfer" when it

is implanted into a recipient other than the donor of the ovum.[2]

The [illegible] question in question were developed originally as "therapeutic" response to female infertility: worldwide, upwards of five hundred infants, including twins, triplets, quadruplets, have been born to "infertile" women as a result of use of these measures. They are helpful now as well in diagnosing causes of infertility and as source of materials for scientific and clinical research.[3]

Considered in the wider ethical context, such extra-corporeal fertilization allows external manipulation of ovum-sperm components such that ovum and sperm "donation" to the fertilization process are possible, as is extensive research using ovum, sperm or fertilization activity separately or conjointly. Since implantation following IVF originates extra-corporeally, single or multiple embryo replacement or transfer, embryo discard and embryo research are all options; development of embryo storage procedures (cryobanking) allows elective time delay in regard of each activity noted.

Question Two

Is the extra-corporeality of IVF-ER/T activity ethically suspect?

Stated more directly, "Is explicit separation of sexual intimacy from human procreation ethically acceptable?" The range of ethical response is wide.

Those responding positively may be concerned with the inner dynamic of such activity and/or with its possible consequences. Such persons may view IVT-ER/T procedures as violating accepted ethical norms regarding the inter-sexual-parental relationship;[4] they may find undesirable any mechanized separation of the components of the "normal"/"natural" procreative process. Some may respond positively out of concern for the possible social consequences of such activity:[5] possible disruption of present parenting or family concepts, e.g., possible shift in the limit of human research activities.

A negative answer to the question may come from those who fail to perceive a distinction between scientific achievement and ethical implication such that "is" equals "ought". Others may dispute the norms or consequences already mentioned. Some may argue that an accepted precedent for such extra-corporeal procedures exists in use of artificial insemination procedures. There are those who will ground such a response in the perceived good consequences of such activity or who see such consequences as reinforcement of the view that this technology is a triumph of human skill and human choice.[6]

Some allege, "It all depends". In the end, of course, action must be taken so "It all depends" falls back on some norm to be identified, a norm which must be universal, not exceptional. More fundamentally, in ethical response to ethical question, the response, "It all depends"/"It is indifferent" is not acceptable.

As basic to all ethical questions about IVF-ER/T, the physician must first answer: "Is the extra-corporeality of these procedures ethically suspect?"

Question Three

Is IVF-ER/T properly identified as "therapeutic procedure"?[7]

There are two routes for response here. A first query might be: as regards female infertility, are these procedures regarded "curative"? A second query might be: "As contrasted with clinical research (therapeutic/non-therapeutic), are these procedures non-experimental? At issue, of course, are the criteria for defining "therapy" as distinct from "non-therapy" and for defining "therapy" as distinct from "experiment" (research). Who delineates such criteria; what shall they be?

In response to the first sub-query: some allege that while the "produced pregnancy" alleviates psychological/social distress (and is thus "therapeutic"), such a procedure does not remedy the underlying cause of such distress (infertility, by reasons anatomical or other) and is thus "non-therapeutic").[8] If the position is sustained, there are implications for the identity (professional or other) of those who dispense these procedures, e.g., implications concerning payment for such services in "health insurance" schemes, etc.

In response to the second sub-query, the three professional papers provide cumulative conceptual.

The British Medical Research council (BrMRC) identifies IVF-ER/T as therapeutic ("in the context of female infertility due to tubal occlusion"),[9] no definition of "therapeutic" given.

The British Medical Association (BMA) identifies the techniques as "new and still developping". It is concerned with success ("only about one in five IVF-ER leads to an established pregnancy, and the miscarriage rate is about twenty-five percent higher than normal") and with risk ("laparoscopy and the other procedures of IVF-ER... are not without risks").[10]

The Royal College of Obstetricians and Gynaecologists (RCOG) is likewise concerned with success and risk. Pregnancy is achieved after one laparoscopy in twenty-twenty-five percent of patients, but of these, some thirty percent abort before the tenth week and some seventy percent proceed to viability. The group disputes any question of high risk of physical abnormality for IVF-ER children, but grants the risk of multiple pregnancy to mother and babies resulting from the introduction of two or more embryos into the uterus at the same time. The RCOG notes that such risk is to be weighed against the potential benefits of the procedure, just as risk/benefit judgments have been made in the past in "many other aspects of medical practice". In this connection, "informed consent" permits such risk-taking, even as it did previously in the "early stages of development of techniques of gonadotrophin stimulation of the ovaries when superovulation frequently resulted in multiple pregnancies". As a final note, the RCOG comments: "Research in this field is still proceeding and we look forward to the day when the implantation of one zygote will produce one live infant in such a high proportion of cases that multiple implantation and the danger associated with subsequent multiple pregnancies will be eliminated".

In summary, there is notional confusion here in response to the second sub-query. The first distinction required is that between therapy and research in the matter of uncertainty and risk. Granted a certain element of risk and uncertainty associated with any therapeutic procedure: when is that exceeded such that the procedure is no longer therapeutic but instead experimental? The second distinction required is that between acceptable and non-acceptable experimentation. What level of risk separates them? In making this judgment, it

should be noted that while informed consent is a necessary ingredient in all ethical experimentation, of itself it is not sufficient to render all experimentation thereby ethical.

The fundamental difficulty for the physician here remains. There are two sets of ethical norms, both professionally-accepted: one governs ethical behaviour in therapy;[12] one governs ethical behaviour in research.[13] Just as IVF-ER/T cannot be both therapeutic (BrMRC) and experimental (RCOG) at the same time and in the same respect, notionally speaking, so the ethical physician cannot be bound to work under two quite different standards for behaviour when using the techniques in question.

As basic to ethical behaviour, the physician must answer the question: "Is IVF-ER/T properly identified as 'therapeutic procedure'?"

Question Four

Is the relationship among participating adults relevant to ethical judgment about IVF-ER/T?

It is apparent that the outcome desired in pursuing the IVF-ER/T procedures is a child. Traditionally, in this society, the welfare of the child has some precedence over adult preferences in behaviour. Implicitly, both the BMA and RCOG subscribe to this view in advocating certain relationships among those adults who "contrive" the child.[14] (The ethical force of "child well-being" here and the reasons for concern about it are not clearly specified in the documents). Both groups agree that "marriage" is the desirable social state in which child-conception is to be undertaken.

The RCOG defines "marriage" as a "heterosexual couple cohabiting on a stable basis, whether or not legally married".[15] BMA proffers no definition: continuing reference to "partner", "relationship" allows the inference that it shares the view of the RCOG regarding "marriage".

Given counselling of patients, patients' consent and professional acceptability (a point for later discussion), the BMA and RCOG find no ethical objection (give ethical approval) to the use of IVF-ER within "marriage", using gametes of the "marriage" partners.[16]

With the consent of all concerned (and appropriate counselling and professional acceptability), both groups would allow use of donor ovum or donor sperm for the practice of IVF-ER/T in "marriage", the RCOG noting no ethical difference between such practice and the "accepted" practice of artificial insemination by donor (AID). Further, should neither partner be able to produce viable gametes, then "in rare cases", the BMA would allow use of both donor ovum and donor sperm in the one procedure. The RCOG agrees, but would find it "undesirable" and "rarely justified" to use gametes from sibling, relative or known friend (reasons not given).[17]

"Exceptionally" and with "grave reservations" (since it "believes most practitioners will intuitively feel that IVF and ER should be performed in the most 'natural' of family environments", the RCOG would allow use of IVF-ER "without marriage", i.e., in the case of single women. In its comments, the RCOG notes that the "natural situation is for a child to have two parents. Though single-parenthood frequently results from natural conception without marriage this is an entirely different thing from 'professional contriving' to produce the same result". However, the RCOG argument continues, the doctor's discretion is not to be limited here by "blanket exclusion from treatment of single women"; further, society has a "variety of family forms... adoption by single people, though rare, is possible".[18] Since the BMA document speaks only of "partner" and "relationship", the inference is that the BMA does not approve of IVF-ER/T in the case of single persons.

Both the BMA and RCOG specifically and unequivocally reject the practice of surrogate motherhood in connection with the IVF procedure (IVF using sperm and ova of a couple with transfer of the embryo to the uterus of another woman who might carry the embryo to term on behalf of the couple). The BMA "has yet to be satisfied" that the practice "will ever be acceptable". The RCOG argues against the practice, citing the legal and psychological difficulties for the "surrogate" child conceived by adultery or by artificial insemination by donor as precedent; unenforceability of any legal contract in this regard, possible emotional stress for the surrogate (should she not wish to surrender the child), possible emotional stress for the couple (should the surrogate not surrender the child), possible commercial exploitation, are all mentioned.[19, 20]

It is not without interest to note the ACOG (American College of Obstetricians and gynecologists) comments in regard of surrogate motherhood. Citing many of the difficulties already noted, the ACOG has "significant reservations about this approach to parenthood": at the same time, it recognizes the decision to participate as "an individual one for each physician to make".

By way of summary here, there are several sub-queries the physician must answer:

1. Insofar as child-conception is concerned, ought individual physician or professional groups whether in individual cases or generally, set aside "legal marriage" as society's traditionally-"approved" milieu?
2. In discussion of IVF with embryo implantation as involving use of donor (ovum, sperm or both), is the precedent of artificial insemination validly used? First, is artificial insemination by donor acceptable within either "legal" or "commonlaw" marriage insofar as inter-partner relationships are concerned? Is the evidence that AID-conceived children do not suffer harm by reason of their AID-conception conclusive?
3. Does "child well-being" have priority as criterion in judging the ethical acceptability of adult relationships in all "therapeutic" use of the procedure? Does this priority prevail when "physician discretion" is the standard used in judging the acceptability of IVF-ER/T in the case of the single woman?
4. Will the ACOG standard of "individual choice" (RCOG "physician discretion") as prevails regarding the practice of AID-surrogate motherhood not also prevail as regards the practice of IVF-ET/surrograte motherhood? Why?
5. Not mentioned in discussion of relationships here were the issues of anonymity and confidentiality. Will scrutiny of the difficulties in these matters as encountered in the practice of artificial insemination by donor be helpful?

Resolution of these difficulties is part of the physician's reponse to the overall question: "Is the relationship among

participating [illegible] relevant to ethical judgment about IVF-ER/T"?

Question Five

What uses of excess IVF material are ethically acceptable?

In attempting successful IVF-ER/T outcome, excess ova, sperm, embryos may be acquired:[21] the question of their disposition thus arises.

Cryostorage of such material against later use towards live birth has support here, albeit on a time-limited basis, [22] but such storage is not without risk to the conceptus as both the BrMRC and RCOG indicate.[23] Even with successful cryostorage, the problem of ultimate disposition remains.

Selective destruction of embryos, for whatever reason, is implicit in the practice of elective abortion; it is probable that use of IUD as contraceptive measure also destroys many embryos. In this present context, however, the RCOG argues that the excess IVF embryos should not be allowed to die because "scientists who have made possible the creation of embryos would consider this a waste of useful material from which valuable information might be obtained". Further, "those who believe life 'begins at conception' would find it deeply disturbing to create life only to destroy it when it proved unwanted"[24]

Donation of the embryo is discussed briefly and dismissed as unacceptable "if a sibling pregnancy is already established",[25]

The RCOG presses its case for research-use of these embryos along several lines of argument. Neither the embryo's "genetic coding as unique human being" nor its physical development warrant giving the embryo "protection due a human being". Again, "it is morally unconvincing to claim absolute inviolability for an organism with which nature itself is so prodigal".[26] All of this being said, the RCOG argues that "human reason and conscience (not law) must determine when it would be wrong to carry out biomedical research (using the embryos)".[29] That judgment must relate to the embryo's growth, especially its neural development. Any guidelines derived here must "reflect the status of the embryo in our scale of values", even as they must be sensitive to public sentiment.

All three groups prohibit experimental or manipulative use of the embryo prior to its transfer to a uterus.[28] Many useful projects are suggested for experimental investigation (e.g., genetic study, improvement of the *in vitro* nutrient media, interspecies fertilization in aid of male subfertility); in the future, preventive manipulation of the pre-implantation embryo's genetic structure may be possible as may use of such embryo's cells in aid of ill children.[29] Whatever the research project planned, all agree that it should be scientifically sound with a goal clearly-directed to clinical problems. The BrMRC notes that in using such material, it should not be "stored for unspecified research use".[30]

The issue of consent is addressed in all three documents. Each group calls for consent in the use of fertilised ova; the BrMRC seeks consent "in every case" involving use of donated ova or sperm.[31]

There is a difference expressed concerning approval of research ethics committees in connection with this work. The BMA sees such approval as the responsibility of the "local ethical committee" (likely within a university teaching hospital complex); the BrMRC seeks approval from "appropriate scientific and local ethical committees".[32]

In principle, the BMA and RCOG give specific approval to the work of the BrMRC.[33]

For the physician seeking to make ethical judgment in this matter of disposition of the extra embryo, there are several sub-queries:

1. What is the moral status of the embryo? It appears both wanted and unwanted, protectable and discardable. As extra, is research-status preferable to death? Is "deposit" in the embryo-bank, awaiting "adoption" by foster-parents preferable? What is the point at which the young human being can claim as moral right protection against its manipulation, its imposed loss of life?
2. What is the purpose of "parental" consent here? Is it for the protection of "parental" property, for protection of the embryo against certain unacceptable experimentation, for protection of the researcher/clinician/institution/donors against liability?
3. What criteria will govern implantation of the manipulated-embryo as present research is perfected?

Overall, the physician must answer the question: "What uses of excess IVF material are ethically acceptable"?

Question Six

What basis is there for a "medical-ethics" dimension in use of IVF-ER/T?

The fact that each of the three groups address the implications of IVF-ER/T practice under the category, "ethical", supports the view that these groups perceive an ethical dimension here. In that vein, each group identifies various ethical issues, providing direction in regard of each of these areas.

Grounding such concern, two concepts seems to prevail:

1. The physician's activity in this regard is not technical merely. The RCOG makes the point: "Doctors are not acting (here) only as enablers... in IVF and ER/T they are taking part in the formation of the embryo itself. That role brings a special sense of responsibility."[34]
2. Physician responsibility here requires the practice of "physician discretion". Such responsibility/discretion entail "assessment of the stability of the family relationship of the couple concerned and of the sincerity of their intention to accept the duties and obligations of parenthood". Again, "There may be strong adverse indications of a social nature, or in the history of the marriage, which would seriously jeopardise the interests of the child to be born from the procedure, and hence outweigh the desires of the couple themselves. It remains the province of the doctor, in consultation with appropriate counsellors, to decide whether or not he should agree to their request".[35]

As regards the second sub-topic here, the role of physician as "ethical gate-keeper" is worth reflection. Some will reject the role in this context: "the question remains whether anybody possesses the insight and understanding to determine in advance that the claim of one couple to bear a child is inferior to that of another".[36] Speaking more generally, however,

when there is insistence that practice of IVF-ER/T is not without ethical implications, and when physicians accept that view, it is inevitable that the physician shall be an "ethical gate-keeper" in some sense. The basis for such activity must be clarified and it must be publicized as befits any such professional undertaking.[37] Its implications as regards practice of IVF-ER/T must be the subject of ongoing query.[38]

In the end, the physician must answer the question: "What basis is there for a "medical-ethics" dimension in use of IVF-ER/T?

Notes

1. (British) Government inquiry into human fertilisation and embryology (Warnock Committee), 1982 Terms of reference. *cf.* Ramsey P. *et al*: *In vitro* fertilization: Four commentaries. *HCR (Hastings Center Report)*, 7-14, October 1978.

2. British Medical Association Working Group on *in vitro* fertilisation: Appendix VI: Interim report on human *in vitro* fertilisation and embryo replacement and transfer. *BMJ 3*:1594-5, 14 May 1983. (cited as BMA)
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   cf. Leeton, John F., Trounson, Alan O. and Wood, Carl: IVF and ET: What it is and how it works, in Walters, William A. and Singer, Peter : Test-Tube Babies, Oxford U. Press Oxford, 2-10, 1982.

3. Leeton *et al.*, 8.

4. Morgan, John L.: The created individual: are basic notions of humanity threatened?" Walters and Singer, *op. cit.*, 88-96.
   Hellegers A.E. and McCormick R.A.: Unanswered questions of test tube life. *America 139*:77, 1978.
   Ramsey P.: Fabricated Man: The Ethics of Genetic Control. Yale Univ. Press, New Haven, 33, 1970.
   Walters L.: Human *in vitro* fertilization: A review of the ethical literature". *HCR 9,4*:25, 1979.

5. Kass L.R.: Making babies — The new biology and the 'Old Morality'. *The Public Interest 26*:49, 1972.
   Henley, John A.: *In vitro* fertilisation and the human family: possible and likely consequences, in Walters and Singer, *op. cit.* 79-87.

6. Fletcher, Joseph: The Ethics of Genetic Control: Ending Reproductive Roulette. Anchor Press/Doubleday, Garden City, N.Y., 36, 1974.

7. ET is presently considered sufficiently novel to warrant specific publication notice. *cf.* Trounson A., Leeton J. *et al.*: Pregnancy established in an infertile patient after transfer of a donated embryo fertilised *in vitro*. *BMJ 286*:835-6, 12 March 1983.
   Exclude the experimental freezing of embryos. *cf.* Question 5.
   cf. Dickens, Bernard M.: What is a medical experiment? *CMAJ 113*:635-639, Oct. 4, 1975.

8. *cf.* Edwards R.G.: Fertilization of human eggs *in vitro*: Morals, Ethics and the Law. *Quaterly Review of Biology 49*:9-11, 1974.

9. (British) Medical Research Council Statement: Research related to human fertilisation and embryology. *BMJ*, background, 20 Nov. 1982.

10. *BMA*, #4 and 7.
    cf. Leeton *et al. op. cit.*

11. RCOG 11.2; 2.1-2.6.
    cf. Tiefel, Hans O.: Human *in vitro* fertilization: A conservative view. *JAMA 247,23*:32325-3242, June 18, 1982.

12. *cf.* Code of Ethics, Canadian Medical Association, June 1978.

13. *cf.* The Declaration of Helsinki (1975 revision), The Nuremberg Code of Ethics in Medical Research.

14. *BMA* by proscription, e.g. #13.
    RCOG by proscription, e.g. 7.6, *cf.* 3.5; 6.

15. RCOG 3.1.

16. RCOG 3.3; 3.6.
    BMA 8.

17. *BMA* 9.
    RCOG 5.1-5.9.
    The discussion now turns to ET. Beyond the specialized use of ET in surrogate motherhood, ET could be practised with the ovum of a donor fertilized *in vitro* and placed within another female via implantation. ET could also be practised by removing the fertilized ovum (fertilization *in vitro* or *in vivo*) from the uterus of one woman and placing it within another. *cf.* Buster, John F.: Non-surgical transfer of an *in vivo* fertilized donated ovum to an infertility patient. *Lancet 8328*:816-7, Ap. 9, 1983.
    In reference to AID as ethical precedent, some question its acceptability in terms of its possible effect on the child. RCOG notes in this connection: "No satisfactory formula has yet been devised for the assessment of children born as a result of AID" (10.2).

18. RCOG 6.1-6.4. ET not mentioned here.

19. *BMA* 13.
    RCOG 7.2-7.6.
    The RCOG speaks of "difficulties" for the child born via surrogate motherhood "either as a result of adulterous conception or of AID from the intended father". Since RCOG approves AID, the difficulties appear to stem from "surrogate"-status. BMA does not discuss surrogate motherhood via AID; it, too, has approved AID in the past (1973).
    The American College of Obstetricians and Gynecologists (ACOG) discusses surrogate motherhood via AID as the "most common example". It has "significant reservations about this approach to parenthood"; at the same time, it recognizes the decision to participate as "an individual one for each physician to make". If "individual choice" is the standard the group adopts towards AID/surrogate motherhood, one might infer the same standard with regard to IVF-ET/surrogate motherhood unless the special difficulties of the IVF-ET technique would be raised?
    (American College of Obstetricians and Gynecologists: Statement of Policy: Ethical issues in surrogate motherhood. 2 at col. 2, May 1983.)

20. In general, regarding AID/surrogate motherhood, not necessarily IVF-ET/surrogate motherhood,
    cf. Robertson J.A.: Surrogate mothers: Not so novel after all. *HCR 13,5*:28-34, October 1983.
    Kimmel H.T.: The case against surrogate parenting. *Ibid* 35-39.
    Annas G.J.: Contracts to bear a child: Compassion or commercialism? *ibid.* 11.2, 23-4, April 1981.

21. BMA 10, 11.
    BrMRC ii, iii.
    RCOG 11 and 13.

22. BMA 11.
    RCOG 11.1-11.4.
    cf. CIBA Foundation 52. The Freezing of Mammalian Embryos. Elsevier, North Holland, 1977.
    cf. Leeton *et al., op. cit.* 9-10.

cf. Edwards R.G. and Steptoe P.C.: The relevance of the frozen storage of human embryos, in CIBA, 235-250.

23. BrMRC v.
RCOG 13.7.

24. RCOG 13.2.

25. RCOG 13.1; 11.4.
Implicitly, the larger question of donation in the absence of known siblings is raised.

26. RCOG 13.6.

27. RCOG 14.4.6; 13.3.
cf. Edwards R.G. and Purdy J.M., eds.: Human Conception *In Vitro*. Proceedings of the First Bourn Hall Meeting, Academic Press, London, 380, 1982.

28. BrMRc i.
MBA 14.
RCOG 13.8.

29. BrMRC vi.
BMA 10.
RCOG 13.7.

30. *BMA* 10.
RCOG 13.8.
BrMRC iv.

31. BMA 10.
BrMRC ii, iii.
RCOG 13.8; cf. 14.4. 3-4 and 4.3.

32. BrMRC ii.
BMA 12.

33. BMA 15.
RCOG 13.8.

34. RCOG 6.1.
cf. Steptoe P. and Edwards R. correspondance: Pregnancy in an infertile patient after transfer of an embryo fertilized *in vitro*. *BMJ 286*:1351, 26 Apr. 1983.

35. BMA 6.
RCOG 3.5; *cf.* 6.2.

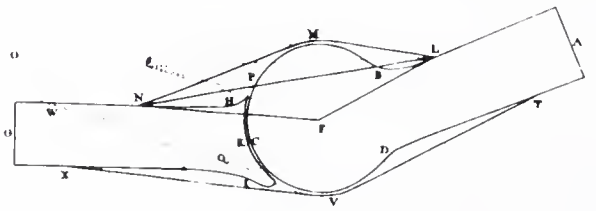
36. Henley, *op. cit.* 82.

37. *cf.* RCOG 1.1-1.2.

38. *cf.* Walters and Singer, *op. cit.* 40. One option is to question the whole procedure (Sir Frank Little).
cf. ibid, Appendix II: Ethical Guidelines for Clinicians and Scientists involved in IVF and ET, 146-7.

vi **INTRODUCTION.**

LET *ABCDA* be a Bone, having a round head *BCD*; the Center of this Head *F*, if the Head be ſpherical; if cylindrical, let the Axis of it paſs through *F*, and be perpendicular to the Plane of this Scheme. Let *GHKIG* be a Bone, having a hollow *Sinus HKI* adapted to the Head *BCD*; ſo as to form a Joint. Let *LMN* be a Muſcle not paſſing through the point *F*, nor yet the Axis drawn through *F* perpendicular to the Plane of this Scheme. Let the Joint be bent, till the Bone



GK be removed into the Situation *OPQO*, and the Muſcle obtain the Situation *LMS*: Then, I ſay, the Muſcle in the Situation *LMS* is ſhorter than in the Situation *LMN*. Draw *FL*, *FN*, *FS*, *LN*, *LS*: then in the two Triangles *LFN*, *LFS* the Side *LF* is common to both, and the Sides *FN*, *FS* equal, but the Angle under *LFN* greater than that under *LFS*; wherefore the Baſe *LN* is greater than the Baſe *LS*: And beſides, the Angle under *FLN* is leſs than that under *FLS*; ſo that the point *M* is farther diſtant from the Line *LN* than from *LS*. Therefore if the Figure *LMS* were ſo applied to the Figure *LMN*, that the point *L* remained common to both, and the Line *LS* fell upon *LN*, the Line *LMS* would fall wholly within the Line *LMN*, though the point *S* were to fall upon the point *N*; but the Lines *LMS* and *LMN* would likewiſe be concave towards the ſame Part, therefore the Line *LMS* would be ſhorter than *LMN*, though the point *S* were to fall upon *N*, and the Line *LS* were equal to *LN*, but *LS* is leſs than *LN*; whence the Line *LMS* will be ſtill ſhorter than *LMN*.

UPON the ſame Principles the Muſcle *TVW*, on the other ſide of the Joint, connected to the Bone *AC* in *T*, and to the Bone *OPQO* in *W*, will be ſhortened, when the Bone *OPQO* is reſtored to the Situation *GK*, and the Muſcle have the Situation *TVX*.

FROM all this it is evident, by the Principles of Mechanics, that when the Muſcle *LMN* contracts it ſelf, if it be not directly over the Axis of the Joint's Motion, it will inflect the Joint, drawing the Bone *GK* towards the Situation *OPQO*; and the Contraction of the Muſcle *TVW* will extend the Joint, by reducing the Bone into its original Situation. By its farther Contraction the Joint will be bent the contrary way, except the form of the Joint, and the Ligaments, by which the Bones are connected, prevent it.

IT

W. Cowper, *Myotoma reformata*, R. Knaplock, London, 1724.

INTRODUCTION. vii

IT is here to be obſerved, that the Muſcles are uſually connected to one of the Bones very near the Joint, by which means the Flexors of the Joints are preſerved contiguous to the Bones in all their Motions. When both the Extremities of a Muſcle are far diſtant from the Joint, the Muſcle is bound down to the Joint by a Ligament. In this caſe the Method of ſhewing, how the Inflection of the Joint ſhortens the Muſcle, muſt be ſomething different from the foregoing: But the principal Alteration required is, that inſtead of the Line *FL*, which is common to the two Triangles *LFN*, *LFS*, the Line muſt be taken, which will join the point *F*, and the place of the Muſcle inveſted by the Ligament; becauſe the diſtance of the Ligament from that Extremity of the Muſcle, connected to the Bone, from which the Ligament takes its riſe, remains always near the ſame.

BUT now this confining of the Muſcles down to the Bones anſwers two very valuable Purpoſes; one is, that the ſmall degree of Contraction, it was proper to allow the Muſcles, may give to the Joints a ſufficient Motion; the other, that the Figure of the Limbs may be preſerved. But then this conſequence on the other hand follows from hence, that the Reſiſtance, which is applied to the Extremity of the moveable Bone of any Joint, and is ſupported by the Muſcles of that Joint, bears but a ſmall proportion to the force required in the ſuſtaining Muſcles. In the preſent Figure, ſuppoſing the Bone *AC* to be fixed, the other *GK* will perform the Office of the mechanical Power, called the Lever; of which *F* is the Fulciment, by which it is ſuſtained, *N* the point to which the moving Power is fixed, acting obliquely in the direction of the right Line *NM*. If a Reſiſtance be applied to the Extremity of the Bone *G*, then by the Principles of Mechanics the force of the Muſcle, acting in the direction *MN*, will be to the Reſiſtance in *G*, when the force of the Muſcle and Reſiſtance are in *Æquilibrio*, as the Perpendicular let fall from the point *F* upon the Line, in whoſe direction the Reſiſtance in *G* is applied, to the Perpendicular let fall from the ſame point *F* upon the Line *MN*. For inſtance, if the Bone *GK* be held parallel to the Horizon, and a Weight be ſuſpended, by the action of the Muſcle *LMN*, at the Extremity of the Bone *G*; becauſe in this caſe the Direction, in which the Weight reſiſts, is perpendicular to the Bone, the force required in the Muſcle *LMN* to ſuſpend the Weight applied in *G* will be to that Weight, as the whole diſtance of the point *G* from the point *F*, to the perpendicular let fall from *F* upon the Line *MN*.

IN the ſame manner may be found the Power required in the Muſcle to ſupport the Weight of the Limb in any Situation; for that Power of the Muſcle will be to the Weight of the Limb, as the Perpendicular let fall from the Center of the Joint upon the Line drawn perpendicular to the Horizon, through the Center of Gravity of the Limb to the Perpendicular let fall from the Center of the Joint upon the part of the Muſcle, that lies in the direction of its Action.

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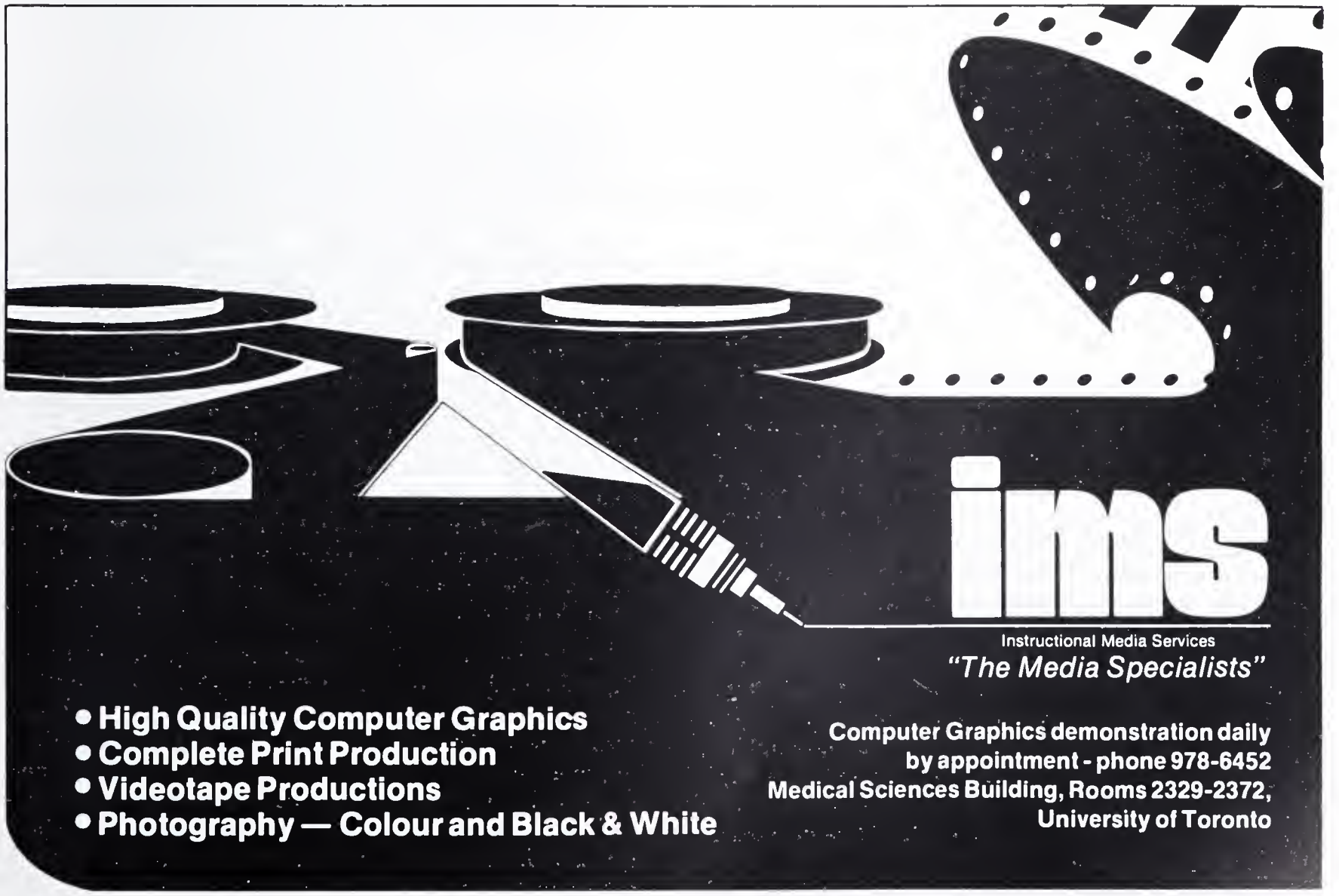
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MEDICAL JURISPRUDENCE

In Vitro Fertilization — Legal and Ethical Issues

Bernard M. Dickens, Ph.D., LL.D.*

The consideration of legal, legislative and ethical issues in I.V.F. must be undertaken with awareness of how the technology relates to other issues of artificial insemination with donated sperm and ova, of surrogate prenatal motherhood and non-genetic parentage, and of isolation and preservation of the embryo *ex utero*. This article addresses a number of these issues, although others, such as concern embryo transplantation to a host surrogate mother, and experimentation with products of conception, cannot be pursued here.

Introduction

The practice of *in vitro* fertilization (I.V.F.) has generated rather more anxious social concern than its normal social setting may seem to warrant. In that it affords an infertile woman an otherwise unavailable opportunity to bear her husband's child, it may appear unexceptionable. The practice has been described as offering an artificial fallopian tube. As such, it should be no more a cause of sensation than artifical insemination by husband's sperm.

It may raise special concerns, however, for a variety of reasons.[1] Its potential for use outside marital relationships opens doors to social complexities, and its most efficient conduct through induced superovulation leading to surplus conceptuses (which here will be described in traditional although biologically inaccurate form as "embryos") raises questions of their disposal. Above all, however, it makes visible a process which heretofore occurred only within the inaccessible darkness of a woman's body, and makes tangible a unique human life at its inception. The contrast in public imagery between the privacy and intimacy of a woman's reproductive system and the sanitized brightness of a populated laboratory is too sharp to escape comment and sensationalization.

I.V.F. is also linked with surrogate motherhood in an association of methods of non-traditional conception and parentage which makes social workers among others apprehensive.[2] When the only legal means by which the infertile could rear children was by adoption, social workers and the courts could control which adults become responsible for the welfare of children of whom they were not natural parents or step-parents. The new reproductive technologies evade these public gatekeeping functions of public or quasi-public agencies, and may permit children to pass under the guardianship of those who would not be acceptable as adoptive parents. In part, this is because scarcity of adoptable children has made qualifications for adoptive parenthood artificially high. It remains the case, however, that those who by any measure would be unsuitable for parenthood, and whose children would be taken from them into protective care at or soon after birth if conceived and born naturally, may have children by modern reproductive means at their own initiative. Such children may still be taken into care, of course, but it may be questioned whether costly resources should be devoted to their artificial conception.

*Professor of Law, Faculty of Law, Centre of Criminology and Faculty of Medicine, University of Toronto

It is ironic that I.V.F. is coming under legal and ethical scrutiny at a time when it may be superseded in clinical preference. More successful and simple than I.V.F. may be *in vivo* fertilization, perhaps by artificial insemination, followed by use of a lavage technique to flush the fertilized ovum from the woman's reproductive tract for transfer to another woman. The recipient may be the wife of the man whose sperm were donated for the insemination. Alternatively, the recipient may be a stranger to a fertile wife inseminated by her husband, artificially or naturally, who cannot bear her own child. Upon birth of the child, the stranger will surrender it to the genetic parents. These relationships, and their obvious variants involving such as family members, duplicate those which may arise in I.V.F. transactions where the embryo will be transferred to a woman other than the ovum donor.

Parents by I.V.F.

It may seem beyond reproach to afford a wife affected by disease or deformity of her fallopian tubes the means to bear her husband's child, and clearly a matter of no legal accountability. Ethical questions may arise, however, where the spouses or either of them have an established history of mistreatment of children. Further, since a number of divorces occurs amounting to 40 per cent of annual marriages,[3] the fact that a married couple seek I.V.F. may not in itself ensure that their children of I.V.F. will be born into a secure social setting. Equally, however, the fact that couples are unmarried in law does not justify the conclusion of instability in their relationships. Indeed, the policy of legislation in Ontario is increasingly to narrow the distinction between married and common law relationships by attaching legal incidents of mutual dependency and accountability to the later that have survived a minimum time, and by reducing almost to vanishing point the difference between legitimate and illegitimate births of children.

Practitioners of I.V.F. may have an ethical rather than a legal responsibility to consider the potential capacity of their patients to offer future children an adequately nurturing environment. The duty exists at the level of macroethics, meaning social or group ethics, rather than of traditional microethics or ethics of individual relationships, since personal ethical duties may not be owable to unconceived children, and duties cannot obviously be owed to individuals to ensure that they are not conceived. It is not self-evident that such a macroethical duty exists, however, since in an analo-

gous field surgeons able to restore women's capacity to conceive and bear children by microsurgical reconstruction or unblocking of the fallopian tubes[4] are not necessarily required to enquire whether the women would make good mothers, or whether they are in stable domestic relationships.

Beyond the problems presented by married couples in unstable unions and unmaried couples in stable unions are those presented by women in lesbian unions[5] and single women seeking asexual pregancy by donated sperm. Similar problems arise when patients liable to transmit genetic or other congenital defects to their offspring seek I.V.F. services with use of donated gametes. These problems have an ethical component, but they are also affected by recent important legislation. The Canadian Charter of Rights and Freedoms after April 1985 will prohibit public discrimination on grounds *inter alia* of physical or mental disability, and provincial Human Rights Codes prohibit discrimination on additional grounds such as marital status. In Quebec, for instance, human rights legislation prohibits discrimination on grounds of sexual orientation. Legislatures may have legal power to override non-discrimination obligations, but may be reluctant to enact or endorse expressly discriminating laws.

Accordingly, existing law protects reproductive rights not only of those within and outside stable unions, but also of those in unorthodox relationships and in no relationship at all, and those affected by a variety of reproductive handicaps.[6] This is obvious where they are capable of natural reproduction, and equally the case when their reproduction depends upon technical services which others may render. Exceptions exist regarding the young and those unable to give legally effective consent, but ouside such protective provisions, which themselves may be ethically questionable as unacceptably paternalistic,[7] people may pursue parenthood with consensual participation of others. No public or other authority may have a duty to make reproductive services available to any potential recipient, married or otherwise, but where individuals can avail themselves of I.V.F. services, deliberate obstruction may violate non-discrimination laws.

Discrimination may be more apparent than real. It has been seen that marriage alone does not entitle a couple to demand access to I.V.F. services, since physicians are not bound to participate for instance in desperate attempts by partners in failing marriages to obligate their partners by conceiving their children. Marriage is not a qualification *per se* for I.V.F., and accordingly refusal to serve the unmarried is not discrimination against them on grounds of their marital status. The critical criteria address the qualitative substance of relationships and stability of individual personalities rather than legal forms. Where applicants for I.V.F. are measured by indications of potential to be adequate parents, and are not rejected on impersonal grounds of marital status, physical or mental status, socioeconomic status, or philosophical, political, religious or other convictions, the decision is unlikely to violate legal requirements. Further, the law is likely to respect conscientious objections of individual practitioners to render services in individual cases, although public agencies may have more binding obligations to make services equitably available.

A duty I.V.F. practitioners may owe their patients is to screen them properly for childbearing and for their genetic and other reproductive potential. Canadian law is becoming increasingly responsive to claims for negligence resulting in conceptions and in births of children parents wished to avoid.[8] Such claims have tended to arise from negligently conducted sterilizations. Although I.V.F. may appear the diametrical opposite, it shares the features that women may be caused thereby to experience particular conceptions they wanted to avoid, notably of foreseeably handicapped children or conceptions which endanger their lives or health, or to give birth to children whose severe abnormalities were predictable before conception. Liability to wrongful conception and to wrongful birth claims by patients may impose upon I.V.F. practitioners a legal obligation to exercise due care in diagnosis and prognosis. Further, negligent conduct of the procedure itself, for instance in management and preservation of the embryo *ex utero* and its transfer to the woman who becomes pregnant, will also justify wrongful conception and/or wrongful birth claims.

Donor gametes

Since a fertilized ovum can be transplanted successfully to the uterus of a woman other than the ovum donor, I.V.F. may be undertaken for a woman in a stable union not only with donor sperm, but also with a donated ovum. Further, both sperm and ovum may be donated. These facts make relevant to I.V.F. all of the legal and ethical issues generated by the long-established but inadequately assessed procedure of artificial insemination by donor (A.I.D.).[9] Ethical sensitivities and bioethical literature have only recently come to be applied in this area, and the law has approached the practice of A.I.D. with wilful blindness and through sometimes inflexible doctrines based upon the sin of adultery rather than the legally unknown experience of asexual reproduction.

The law has traditionally applied simplistic but historically adequate presumptions to paternity. A woman who has become pregnant is presumed, perhaps irrebuttably, to be the mother of the child to which she gives birth.[10] A woman who gives birth while married or within 300 days of her husband's death is presumed, though rebuttably, to have borne his child. A man whose sperm inseminated a woman is father of her child. A father bears responsibility for the support of his child, and may influence his child's rearing, at least in default of the mother discharging parental functions.

These presumptions, while often humanely intended, for instance to afford children certainty of origins, access to support from their natural parents who are presumed to have a natural affinity toward them, and avoidance of the stigma of bastardy, may now have reached the limits of their usefulness. Presumptions are employed in law to fill gaps in knowledge, but with increasing knowledge of asexual reproduction, knowledge of reliable positive as well as negative paternity testing, and knowledge of other means of genetic diagnosis, transmission and tracing, the social, logical and biological incongruities and falsehoods of legal presumptions are easily exposed. Further, evolution in sensitivities has drawn distinctions in parenthood between genetic parenthood, uterine motherhood and postnatal, social or psychological parenthood.[11] These distinctions have exposed socially dysfunctional effects of traditional legal presumptions.

The law is slowly coming to grasp these new realities. It ascribes fatherhood to the man giving a child its male-derived genes, but also places under comparable paternal duties the man who, perhaps through his relationship with the child's mother, knowingly acknowledges the child as a member of his

family.[12] Accordingly, the child may have two men discharging in law legitimate compatible functions of fatherhood. The concept of multiple or collaborative motherhood therefore would rest upon an established experience.

Nevertheless, the law continues to attach responsibilities to biological fatherhood by A.I.D. including by I.V.F., which are primarily financial, and may afford such fathers limited rights. The fact that legal responsibilities have not deterred sperm donation for A.I.D., induced perhaps by no more than a fairly modest payment, is largely because legal responsibilities of fatherhood have been more theoretical than actual, and have passed unnoticed.

They have not been an element in the process of informing donors before they consent to serve as such. Where A.I.D. is used within a married or other stable union, of course, whether by I.V.F. or more traditonal A.I.D., no-one has any incentive to advertise the fact, and in the former the legal presumption of the husband's paternity is especially tenacious. Accordingly, recourse to donor sperm is a fact the law suppresses. This will no doubt continue to be the case even if legislation does not take an increasingly recommended initiative[13] to legislate away the donor's theoretical legal responsibilities, and rights.

Ovum donation is a reproductive novelty applicable both through I.V.F. and *in vivo* fertilization followed by flushing and transplantation of the fertilized ovum. As in the case of traditional A.I.D., however, and in that of prospective donation of both sperm and ovum in a single pregnancy by embryo transplantation, parenthood may legally be observed and registered at birth by reference to social function rather than genetics. Indeed, Ontario's Vital Statistics Act already provides that upon birth to a married woman living with her husband at conception, the name of her husband must be entered in the column of the Register of Births headed "father". There are limited exceptions to this, but they are not applicable to anonymous sperm donation. While this may compel recognition of a genetic falsehood, it may serve a social truth. The Act does not require that the registered fatherhood, or indeed motherhood, shall be genetic as opposed to social or functional. In the past, of course, the two were not distinguishable or severable where motherhood was concerned.

The preference of social over genetic parenthood may be a source of much comfort, but may cause discomfort too. The right of children of A.I.D. and I.V.F. by sperm and/or ovum donation to know the facts and details of their genetic parentage is a matter of legal and ethical uncertainty. This is clearly so where children of such parentage are normally or pathologically curious as to their parentage. The matter may be more grave, however, where they may be affected by a condition whose diagnosis and management are dependent upon genetic information. The risk of offspring being disadvantaged by absence of genetic data may be reduced by careful screening of gamete donors to reduce as far as possible transmisison of adverse genetic traits, and by preservation of data of parental genetic characteristics omitting, however, personal identification.

Screening of gamete donors relates to the issue mentioned above of claims by social parents of severely handicapped children for wrongful birth. Liability rests primarily upon those who recruit and screen prospective donors to exercise due diligence,[14] but donors themselves bear responsibility to be frank and conscientious in giving their relevant family history, and submitting to testing.

The I.V.F. Child

The artificial nature of a child's conception does not affect the child's legal status. It was not always the case, however, that children were spared the legal stigma of their origins in conception. The description of an illegitimate child survived in Ontario until quite recent times, although it was always curious to contemplate "an illegitimate child" — a child that by law should not be a child. In reality, of course, the child was a child of illegitimate parents — parents who by law should not have been parents with each other. This was because they were not married to each other. Partners in I.V.F. are frequently married to each other, however, so that even in jurisdictions which have not taken the step taken, for instance, in Ontario, of terminating the legal status of illegitimacy, children will not be stigmatized. If donated sperm are employed in I.V.F., however, a resulting child technically will be illegitimate where that status remains recognized in law. Since a consenting husband who is infertile or who decides upon genetic grounds not to father a child is legally presumed to be father of his wife's child, and in common with his wife and the anonymous sperm donor has no incentive to allege otherwise, the child will in fact be recognized as legitimate for legal purposes.

An issue affecting a child born of I.V.F. is whether prenatal duties were owed to the child, violation of which can found a successful cause of legal action upon the child's birth. The issue illustrates an number of points of legal evolution. The legal precondition of any complaint is live birth.[15] Accordingly, those claiming to sue on behalf of unborn children, for instance to prevent their abortion, have been held by the courts to have no legal standing in that cause. Once live birth has occurred, the question arises whether legal action can be pursued regarding events which occurred before birth. At one time, courts denied that such action could be taken but they have now generally concluded that it can. A further question, upon which courts are divided in North American jurisdictions, is whether action can be taken regarding events occurring before a child plaintiff's conception. It has been decided, for instance, that when an adolescent female was transfused with negligently mislabeled blood, and over seven years later conceived a child which was seriously affected by blood incompatibility with the mother, the born child had a legal cause of action.[16] Not all jurisdictions accept this principle, however, since some take a more limited view of how far legal liability for misconduct should extend.

Even in jurisdictions willing to recognize pre-conception wrongs, such as negligent handling of sperm or ovum, or negligent screening of a gamete donor, resulting in conception and birth of a severely handicapped child, it remains problematic whether a child's life can be said to be a legally compensable injury. It has been seen that parents can probably succeed in actions for wrongful birth or wrongful conception not resulting in birth, but it is questionable, and in Ontario doubtful, that a handicapped child can sue for what has become called "wrongful life".[17]

The difficulty in the action is that the alternative to the child being born with disability (that is, had the negligence not occured) would not have been normal birth, but non-existence. Another child derived from a different, appropriately selected sperm or ovum might have been born, but not the handicapped plaintiff. The law of compensation is designed to place plaintiffs in the positions in which they would have been had their injuries not occurred. It can quantify in dollar values the difference between normality and abnormality, such as when a normal embryo suffers injury *in utero*, for instance in a road accident, and is born with resultant handicap. The law has much more difficulty, however, in recognizing and compensating the difference between handicapped life and "the utter void of non-existence".[18] It may be argued that the wrong of wrongful life is not the life, but the injury due to negligence. It may also be contended that negligence should not be immune from accountability simply because it results in live birth. Nevertheless, only the state jurisdictions of California and Washington in the English-speaking world have recognized the wrongful life action. It may be doubted that negligence in the operation of I.V.F. in Ontario resulting in birth of a handicapped child which would not otherwise have been born would afford the child a cause of action under present law. The parents might succeed, however, in a wrongful birth action.

The Surplus Embryo

It has been said that "the most ethically and politically controversial aspect of I.V.F. is the status of the embryo."[19] While it may be so, ethical sensitivity about the early embryo may be of recent origin. It was observed in the March 1983 Report of the U.K. Royal College of Obstetricians and Gynaecologists Ethics Committee On *In Vitro* Fertilisation and Embryo Replacement and Transfer, whose members included a distinguished theologian, that:

> [T]he attribution of absolute protection to the human embryo from its earliest beginning has no long history in Western moral tradition. In the tradition, grounded in Aristotelian thought and science, human status was attributed and protection was accorded, as physical development warranted recognition; and the protection became stronger as the fetus advanced stage by stage towards maturity and birth. Knowing as we do that in the natural process large numbers of fertilised ova are lost before implantation, it is morally unconvincing to claim absolute inviolability for an organism with which nature itself is so prodigal.[20]

The legal issue of embryonic status is addressed in the issue of non-implantation disposal of an abnormal or normal but surplus embryo. Australian practitioners of I.V.F. have sought to evade resolution of the issue by maintenance of the *ex utero* embryo in cryopreservation, theoretically in perpetuity, but this still leaves the legal control of the embryo to be determined. Sperm and ova are the legal property of the donors, unless the donors have given or abandoned their property interests to others.[21] When a sperm fertilizes an ovum, however, it is not clear that property interests in it merge, or even survive. Committees considering the ethics of I.V.F. have urged that deployment of embryos should have the approval of the gamete donors,[22] but this may not accord to legal requirements. Even on the plane of ethical perception, it is an important Kantian imperative that people not be treated as property. Treating an embryo as property may indicate its lack of personal status. The point at which an evolving fertilized ovum should be accorded protection due to human life is a matter of important determination.

Some believe this is not an issue for human determination at all, and reflect spiritual concepts of ensoulment to identify human protection as due from the point of conception. Courts traditionally have identified the commencement of protected legal personality at live birth,[23] although the U.S. Supreme Court in *Roe* v. *Wade* (1973) found that constitutional protection of life, liberty and security commenced at the point of fetal viability. This probably means viability independent of mechanical aid, since the early fertilized ovum may be viable *in vitro* and in cryopreservation, and the Court's reasoning considered the form of viability which occurs at about the end of the second trimester of pregnancy.

It cannot be argued in law that an unborn child is a human being. Section 206 of the Criminal Code embodies the general law in its provision that:

> A child becomes a human being within the meaning of this Act when it has completely proceeded, in a living state, from the body of its mother whether or not
>
> (a) it has breathed,
> (b) it has an independent circulation, or
> (c) the navel string is severed.

Before the child becomes a "human being" in law it is still a human child, of course.[24] This observation leaves unaddressed, however, the point at which the human embryo should be regarded as an unborn child, and in particular whether this point in time or development occurs before or only after the embryo has to be implanted in a woman's uterus in order to survive and continue natural growth.

Destruction of the embryo *ex utero* is not homicide, since only human beings are amenable to homicide, and equally it is not legal abortion.[25] In law, namely section 251 of the Criminal Code, abortion is expressed as conduct intended to "procure the miscarriage of a female person". These words must be strictly construed, since the offence of unlawful abortion carries punishment of up to life imprisonment. Courts will not tolerate severe punishment to be imposable upon extended, liberal or imaginative interpretations of language. Since no female person can be described as pregnant when an embryo intended for implantation into her uterus remains *in vitro* or in cryostorage, destruction of that embryo cannot be considered to be intended to procure her miscarriage. Indeed, it appears that removing an ovum fertilized *in vivo* from a woman's reproductive tract before implantation is completed may be legitimate contraception rather than abortion. Answering a Parliamentary Question on post-coital contraception in May 1983, the English Attorney General observed that:

> the word 'miscarriage' is not apt to describe a failure to implant — whether spontaneous or not. Likewise, the phrase 'procure a miscarriage' cannot be construed to include the prevention of implantation... the ordinary use of the word 'miscarriage' related to interference at a state of pre-natal development later than implantation.[26]

This legal analysis opens the way, of course, to flushing techniques being used after *in vivo* fertilization, by artificial or natural means, in order to acquire the fertilized ovum before implantation for transplantation.

The issue of disposal of gametes combined for I.V.F. has been considered by a court, in the case brought in New York by Mrs. Dolores Del Zio against the Columbia Presbyterian Medical Center.[27] The dish containing the ovum and sperm, which may have achieved fertilization although that was not clearly shown, was deliberately emptied without her or her husband's consent. The case was heard by a jury soon after the widely publicized birth in England of the world's first "test tube" baby. The action succeeded in its claim for damages for intentional infliction of mental and physical anguish and $50,000 were awarded. Of particular legal interest is the willingness of the judge to allow a claim for property damage to go to the jury. The jury may have been unimpressed by the claim in that they awarded zero dollars in damages, but it remains significant that the judge considered it a legally proper claim to proceed.

It may follow that a deformed or surplus embryo created in the process of I.V.F. may be disposed of in accordance with the wishes of the genetic donors, and perhaps, if the male donor may be taken to have abandoned his interest to the female donor, in accordance with the ovum donor's wishes. Such wishes are not necessarily spontaneously generated, since those who offer I.V.F. services may indicate their expectations as to disposal of deformed and surplus ova, and admit to their programmes only those gamete donors and recipients who wish to accept them. This leaves open, however, the legal right of patients in programmes to change their minds. In principle, a patient's consent to any form of treatment can be legally withdrawn at any time until the treatment is administered.

Destruction of non-implanted embryos may raise fewer legal problems than their preservation. The use of normal but surplus ova for transplantation to other women than the genetic donors, in order that the recipients may rear the born children as their own, is close to the orthodox scheme anticipated for ovum and sperm donation, and raises few issues if the donors agree.[28] If they are not asked to approve such use, however, problems may arise comparable to those long faced by men who voluntarily took the risk of inseminating women without expressly consenting to parenthood. The analogy is imperfect, not least because of the role of third parties, but it indicates critical issues. No less problematic is use of embryos for research and experimentation. This triggers all of the ethical considerations relevant to fetal research and experimentation, if an embryo is allowed to grow beyond its earliest stages of development.

Access to I.V.F. Services

Once legal non-discrimination provisions have been observed, as discussed above, further questions of access to I.V.F. services may be of ethical content. They may be answered, however, at administrative rather than purely ethical levels, since they concern the basis of governmental provision of services for the infertile. It has been shown that infertility affects one in six or even five couples of reproductive age, and their medical treatment may warrant governmental provision. Traditional artificial insemination services, by husbands' and donors' sperm, are usually covered under provincial health insurance plans, and I.V.F. services may seen to be an equally appropriate charge upon public resources. Indeed, very costly services of microsurgical repair of damaged fallopian tubes are currently provided through a number of provincial health insurance plans, with no special regard having obviously been given to ethical considerations.

Nevertheless, such consideration has been given to the prospect of I.V.F. services becoming available at public expense.[29] The source of infertility the process may remedy may affect whether it ought to be provided. Disease-related fallopian impairment may not be without stigma, since a common source of fallopian damage is venereal disease. Similarly, reproductive injury due to illegal conduct including recourse to drugs or self-induced abortion may raise questions. On the other hand, women rendered infertile due to pelvic inflammatory disease caused by medically recommended use of an intrauterine device may seem worthy of special regard, as a form of medical compensation for iatrogenic injury. Where a woman's life situation makes surgical sterilization a contraceptive option, such as where her family-building appears completed, an unanticipated change in situation, such as divorce followed by remarriage and a wish to have children of the new union, may cause her to seek reversal, and I.V.F. if that is impossible. It has been questioned whether scarce I.V.F. services should be made available to voluntarily sterilized women who have already borne children in priority to innocently infertile women otherwise doomed to involuntary childlessness.

Priorizing between applicants will be an inescapable aspect of conducting publicly provided I.V.F. programmes for some years to come. An alternative source of services may be found, of course, in the private sector, through practitioners who have opted out of provincially funded services. Further, those with means may avail themselves of services provided elsewhere. Canada's first I.V.F. parents, an Oakville, Ontario couple who had twins, acquired I.V.F. services through Dr. Patrick Steptoe in England. Whether private health services should develop in Canada, to parallel and perhaps compete with provincial health plan funded services, is a matter of professional, philosophical and political contention extending far beyond the issue of I.V.F. Whether a province will put resources into I.V.F. programmes when other health services may appear at risk of suffering reduced funding raises important issues of priorities between different populations of claimants for limited resources. Whether provinces should obstruct recourse to private services by those assessed to be a low priority for supply of public services raises key questions of freedom and equity. It also raises distinctions between socioeconomic groups within low-priority populations which provincial health plans were introduced to narrow.

Accordingly, access to I.V.F. services involves a range of issues of principle central to the purpose and practice of governmental provision of health services, and to personal freedom of access to services which only wealthy individuals can afford to purchase but which government cannot or will not make available generally or at all. U.S. experience shows how entrepreneurial freedom may result in questionable and unsuccessful private I.V.F. services being offered to wealthy, strongly motivated and despairing middle-aged couples, and to others who are not wealthy but who will make major sacrifices to pay such medical fees. Governmental quality and other controls may prevent undue exploitation of vulnerable populations of potential patients, but may also decrease private provision of services and raise costs and so exclusivity. It

may be that, beyond the inherent problems of running I.V.F. programmes, their public and/or private provision may present a microcosm of resource allocation dilemmas to be faced in Canadian health care at the imminent approach of the twenty-first century.□

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Answer to Radiology Rounds

(from page 49)

1, 4 and 5. Left sided pleural effusion and diaphragmatic herniation of bowel contents secondary to diaphragmatic rupture.

Fig. 3 To confirm the diagnosis of traumatic diaphragmatic rupture, the patient had a barium enema and contrast material was introduced into the stomach through the n-g tube. The splenic flexure of the colon and a portion of the stomach have herniated into the left hemi-thorax.

The most common cause of diaphragmatic rupture is blunt trauma to the thorax or abdomen during a motor vehicle accident. Sports injuries and industrial accidents comprise 25% of cases. A sudden, dramatic increase in either the intra-thoracic or intra-abdominal pressure causes the diaphragm to tear. Approximately 95% of diaphragmatic ruptures are left-sided, usually at the apex or posterior portions of the hemi-diaphragm. Diaphragmatic rupture is seen in 3-5% of patients admitted to hospital with multiple injuries. The structures that most commonly herniate into the left hemi-thorax (in decreasing order of frequency) are: stomach; colon; small bowel; mesentery; and spleen.

Patients with a diaphragmatic rupture present with a broad spectrum of clinical signs and symptoms. Herniation of abdominal contents can cause no symptoms or lead to a life-threatening situation due to mediastinal compression. Diaphragmatic ruptures are commonly associated with broken ribs, pulmonary contusions, splenic injury and a hemothorax. Strangulation of herniated structures can occur. The diagnostic triad of a mediastinal shift, dullness or tympany to percussion and audible bowel sounds over the thorax is strongly suggestive of a traumatic diaphragmatic hernia.

The findings on plain film examination of this patient's chest are: obliteration of the left hemi-diaphragm; a left pleural effusion; and multiple lucencies, most evident on the lateral film, indicative of bowel in the left hemi-thorax. A naso-gastric tube is demonstrated in the stomach. (Fig. 1 and 2)

To confirm the provisional diagnosis of traumatic diaphragmatic rupture the patient had a barium enema and contrast was introduced into the stomach through the naso-gastric tube. (Fig. 3) In some cases, the position of the naso-gastric tube is sufficient to make the diagnosis. Also, if a contrast agent is passed through a chest tube into the thoracic cavity and visualized in the abdomen on plain film studies, the diagnosis of diaphragmatic rupture is certain.

At surgery there was a large diaphragmatic tear with colon, stomach and spleen present in the left hemi-thorax.□

Acknowledgments

This case of diaphragmatic rupture was provided by the Dept. of Radiology, Sunnybrook Hospital, Toronto.

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PEDIATRICS

Down Syndrome — Informing the Parents

Caroline Despard 8T5

Down Syndrome is a relatively common chromosomal anomaly involving an extra chromosome 21 or part thereof: a trisomy 21, a translocation or mosaicism. The former is more common with an increased incidence in older mothers. A study in the Ontario counties of Essex, Middlesex and Waterloo showed an overall incidence of one in 787 live births.[22] Down Syndrome was chosen for this paper because it can frequently be diagnosed at birth or shortly thereafter, and because of the relatively high incidence. These two factors make the question of how to inform the parents important to all physicians. Nonetheless, some of the findings may relate to other handicapping conditions. Several researchers have written on the experience parents have had when told this diagnosis. They have analyzed the parental preferences on several points to find the manner of informing the parents which would have caused the least dissatisfaction for these parents. The purpose of this paper is to consolidate the results of these studies and to discuss the implications and recommendations for the medical practitioner.

Introduction

The author of this paper is a sibling of a young woman with Down Syndrome and, as such, bias may exist in the opinions expressed.

When a child is diagnosed as having a handicapping condition, the parents turn to the doctor as being the most knowledgeable person on the subject and their best source of information and support. The doctor is, therefore, in an ideal situation to help the new parents deal with the news and learn to accept and love the new member of their family. The sooner the parents adjust to this news and begin to provide for the needs of the child, the better it is for both the parents and the child.[4, 13]

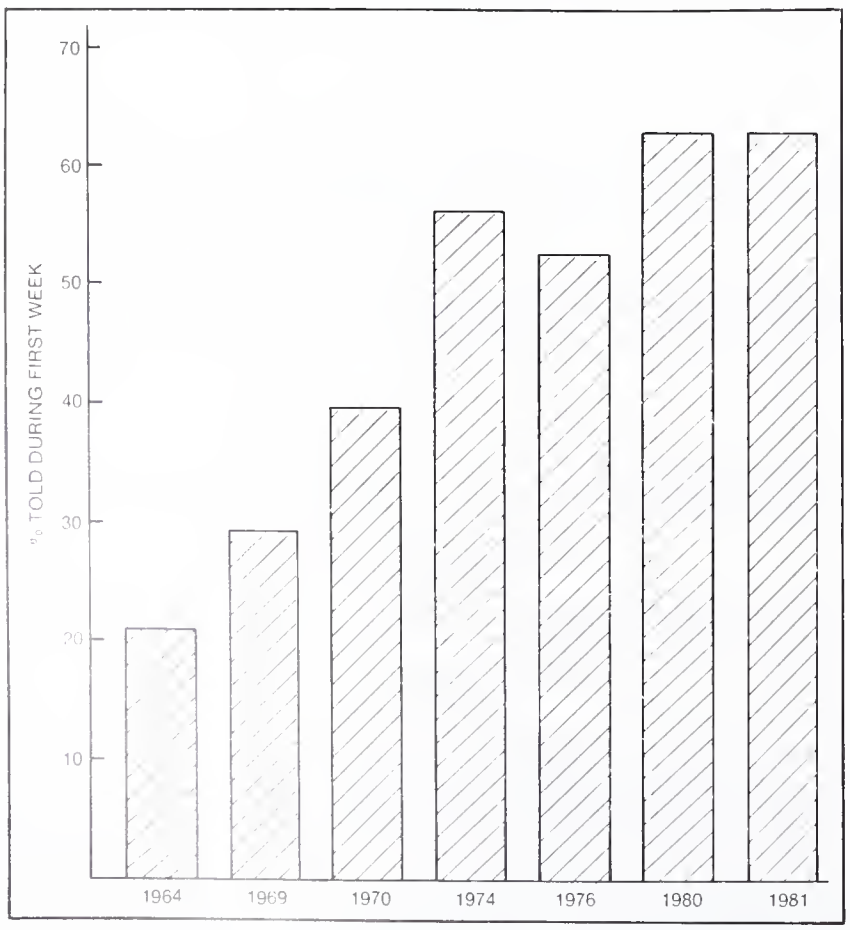

Figure 1. Changes in the pattern of telling parents their child has Down Syndrome. References 6,1,2,10,7,12,18. After Gayton & Walker, 1974.

When to Tell the Parents

Attitudes toward when to tell the parents have changed dramatically since the early 1950s. Franklin (1958) argued that it was better to wait until the mother got to know her baby.[8] Parmelle (1956) disagreed.[17] It was this controversy which sparked the first interest in how to tell parents and the first paper in 1964.[6] The more recent papers, with one exception, agree that the parents should be told as soon as possible.[1, 2, 3, 6,7 ,9 ,16, 18] This is reflected by a trend within the medical profession to tell the parents earlier as shown in Figure 1.

In a 1974 study it was found that 59% of the parents were told in the first week while 31% were told between the first week and the end of the first year. Nine percent found out later.[9] In the same study, 90% felt they should have been told during the first week and ten percent felt they should have been told between the first week and the end of the first year. These figures are sharply opposed to the 59% and 31% experience of the parents.

Parental satisfaction with the way the information was given to them is related strongly to when they were told. Reasons parents gave for being told early included: (1) that they found it difficult to tell people the child had Down Syndrome after already stating the child was fine, (2) that their anxiety when the child failed to develop normally would have been prevented, (3) that they had a right to know if anything was wrong with their child as soon as the physician knew; and (4) that it was all the harder to accept having had time to build false hopes.[3,10]

However, not all mothers preferred to be told immediately. Reasons given for feeling a delay was acceptable included that

they needed to regain strength after the birth and they did not feel it mattered when one was informed.[1] One researcher found that most parents were satisfied if they were told between five days and one month after the birth of the baby. After one month, the proportion satisfied rapidly declined. Notably, five mothers in the study who were told within the first four days, would have preferred to have been told even earlier.[2] Further in support of telling the parents as early as possible, another study found that those mothers who were told within 48 hours tended to be more accepting and felt more positive about their child.[7] While not everyone would be happy with being told immediately, once the diagnosis was known or highly suspected, the evidence points towards telling the parents as soon as possible.

Lucas and Lucas (1980) also found that 50% of a total of six parents who were told immediately after the birth felt feelings of rejection for a while as opposed to 17.4% who were told during the next 24 hours. The period of rejection was not specified, nor the intensity of the feelings. Since other researchers have not reported this relationship and the numbers involved may not be significant, there would not seem to be sufficient evidence to exclude telling the parents at the delivery.[12]

Choice of Place and Amount of Time

It is important that an appropriate place is chosen to speak to the parents. It should be a place where they are not likely to be interrupted: a busy hospital hallway or crowded hospital room is not suitable. Several authors stress the need to have sufficient time to allow the parents to ask questions and to express their feelings. It is important that the parents do not feel that the physician is anxious to leave, as this may be interpreted as being insensitive, lacking in sympathy or being disinterested in their child or their needs.[4, 11,14 ,16]

Who Should Tell the Parents

In a 1974 study, 13% of the parents were told by their spouse, 15% by the obstetrician, 53% by the pediatrician and 16% by others, usually the general practitioner. Seventy-seven per cent were satisfied with who had told them, with the greatest number unsatisfied being those who were told by their spouse.[10] Of the parents in the study, 32% preferred the obstetrician, 38% the pediatrician, 25% either of the former and 2% preferred to be told by their spouse.

There was no clear-cut preference shown for either the obstetrician or pediatrician telling the parents. Parents who said they would have preferred to be told by the pediatrician gave such reasons as: he or she is the one who knows children best, or he or she is the one that they would be returning to for follow-up visits with their child. Those who preferred the obstetrician, stated such reasons as: he or she would have known first and they wanted to know immediately, or that they had known him or her throughout their pregnancy and it was more comfortable to be told by someone they knew.

While there may be little evidence for a preference between obstetrician and pediatrician, writers stress that the early discussion with the parents should not be left to junior doctors, nurses, or medical students, as has happened, as they may not be sufficiently trained or experienced to handle the situation. Whoever tells the parents should be knowledgeable enough about Down Syndrome and mental retardation to answer the questions the parents will pose.[16, 18]

Moreover, it is hardly humane or sensitive to inform the parents by mail or telephone, as has happened to a small number of parents in these papers. Nor should parents learn of the diagnosis by reading their charts as this will create an atmosphere of doubt and deceit between the parents and the medical profession.[6, 7,16]

Sometimes, it is felt that the normal reaction of the parents to the news is to feel resentful towards the informant. This has been used as a good reason for the family physician not to be the one who tells the parents, even though he or she may know them better and be more able to judge the correct way to deal with their initial reactions. One study reported that all the parents who felt that they were told well wanted to talk to the informant again soon afterwards but those who felt they were told bluntly or unsympathetically wanted to speak to someone else.[5] The assumption that strongly resentful feelings against the informant are inevitable may be unwarranted.

However, if we assume that this reaction is expected by many within the medical profession then it is impossible to justify the number of doctors who tell one parent the diagnosis and expect them to tell the other. Obviously this would tend to make the spouse the object of this resentment.

Should the Parents Be Told Together or Separately

Most papers agree that all effort should be made to tell the parents together.[2, 4, 10, 11, 12, 15, 17] As shown in Figure 2, on an average, less than one quarter are told in this way. In the 1974 study, of those parents who showed a preference, 86% would have preferred to be told together. Of the rest, about half believed the father should have been told first and half believed the doctor should tell whomever seemed the strongest.[10] They also found that parents given the responsibility of telling the other found this especially difficult. They were unable to answer the avalanche of questions that their spouse had and were, as a result, the butt of a great deal of anger and hostility.

Unlike the increasing tendency to tell parents as soon as possible, as shown in Figure 2, there is no increased tendency to tell the parents together — an area for further improvement.

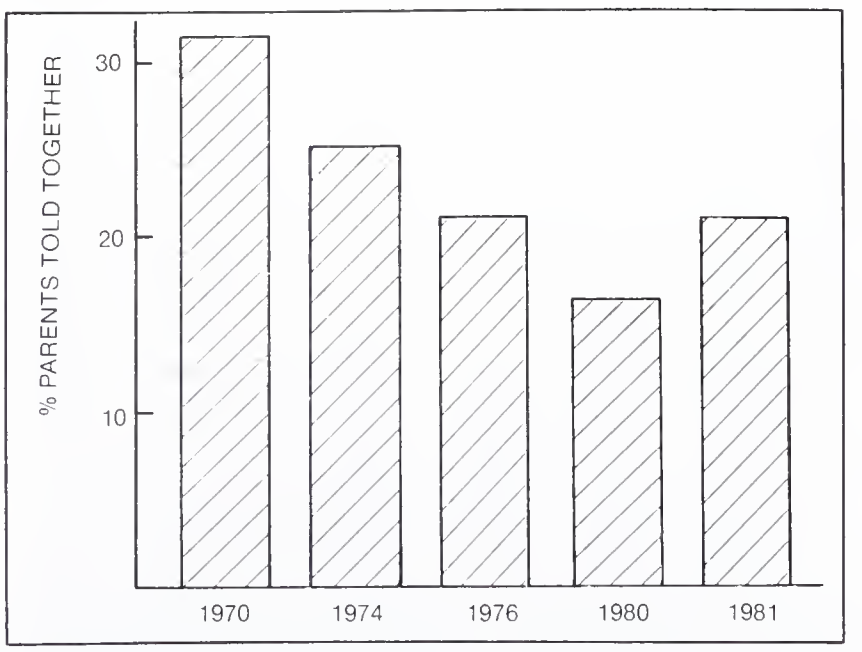

Figure 2. Percentage of Parents told the Diagnosis of Down Syndrome Together. References 2,7,10,12,18

Who Else Should Be There

Most parents felt that the child should be present when they were being told or that they should be allowed to see him or her immediately afterwards.[5, 7]

In the case of a single parent family, the presence of a close friend or relative may be useful. After the initial diagnosis is told, the single parent may prefer to have someone with them to discuss the news further. This is especially true if the parent is to go home after talking to the doctor. No person should be allowed to drive home after receiving distressing news.[4]

Though few writers have considered siblings in their study, one suggested that older brothers and sisters should be present at certain stages of the conversations with the doctor regarding the child's condition. They suggested the parents should have this possibility suggested to them to see if it suits their family. Moreover, they suggested that if the entire family is present while the doctor is giving information on the child's condition, he or she should watch carefully the reactions of the children, direct comments their way and encourage their questions.[11] Too often the needs of the siblings are not recognized either by the doctors involved or the parents. Other members of the family such as grandparents may also have concerns and questions which the parents would prefer answered by the doctor.

Prior Suspicions

When considering how to tell the parents, one tends to presume that they don't know or don't already suspect. Studies indicate that the parents may already suspect that there is something wrong and both waiting to hear what it is and being told by staff that nothing is wrong adds further anguish.[2,6,7,9,10,12]

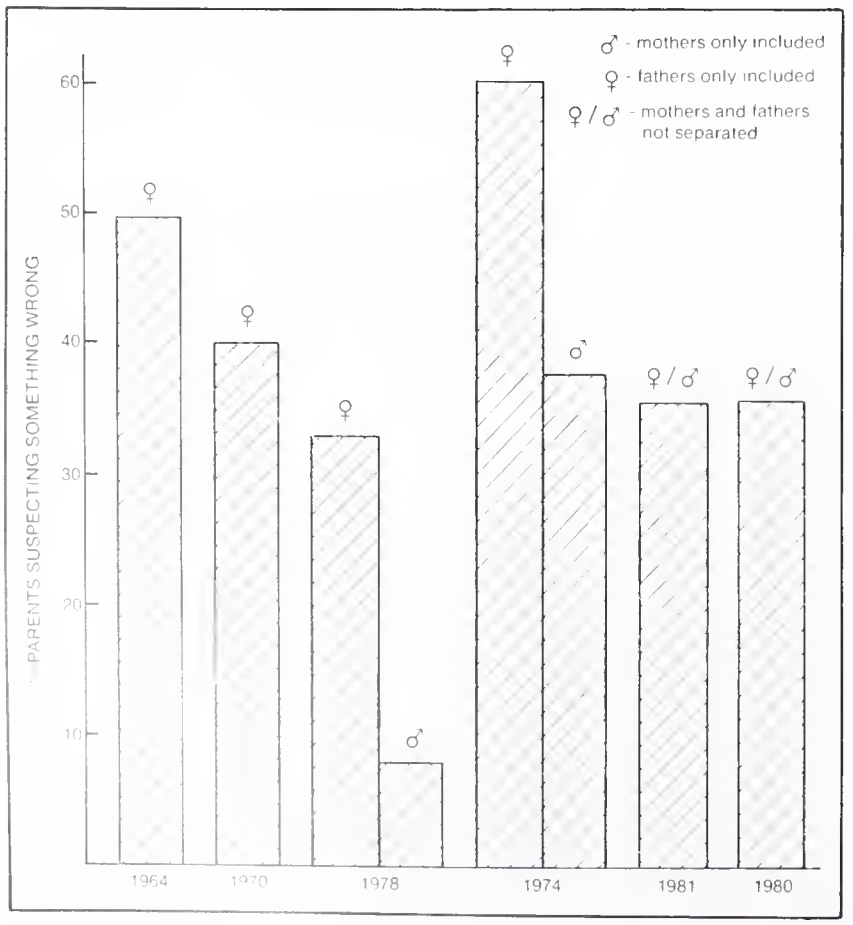

Figure 3. Percentage of parents suspecting something wrong with the child before being informed of the diagnosis. References 2,6,9,10,7,12

As shown in Figure 3, these studies show that close to 50% of parents suspected something wrong prior to being told. The reasons given in these various studies for being suspicious included noticing the stigmata of Down Syndrome, noticing changes in the handling of their child by the medical staff, being transferred to a private room, being treated especially kindly by the nursing staff, difficulties in feeding, having the baby kept from them in the nursery and being worried about advanced age prior to the birth.

The most common change parents noticed was the way the medical staff reacted. Parents noticed extra attention or students, doctors and nurses crowding around the cot, extra concern on their faces, or something alarming about their attitude, differences in hospital routine, evasiveness and falsely reassuring answers to inquiries. There is strong evidence for not falsely reassuring patients. One study reported that those mothers who at the time of the study continued to be resentful and dissatisfied with the way that they were told, were those who suspected all along that something was wrong, who asked about it and were reassured that there was nothing seriously wrong with the child.[6]

How the parents are told

Sympathy, understanding and tact are three essentials when telling the parents that their child has a handicapping condition. As shown in Figure 4, among the most common criticisms of how they were told parents mentioned bluntness and insensitivity.[1,2,6,7,12,18] While it is distressing to tell parents that something is wrong with their child, these studies show that parents are more satisfied if they are told honestly and sympathetically and are likely to feel appreciative if comfort and support are given at this early time.

Figure 4. — Criticisms made by mothers in addition to timing

Criticism	Percentage of Mothers
Given insufficient explanation of condition	14%
Told unsympathetically	6%
First discovered diagnosis accidentally*	5%
Reassured initially that child was normal	4%
Given overpessimistic prognosis	4%
Given overoptimistic prognosis	2%

*From a clinic card (2 mothers), a neighbour (2 mothers) and a magazine (1 mother)

Adapted from Berg, Gilderdale and Way, 1969

The reactions of parents to the diagnosis of Down Syndrome is highly individualistic. It depends on many factors such as personality, marital relationship, feelings about handicaps and others. Certain reactions are more common and the sympathetic doctor should be aware that they exist and deal with them accordingly.

In one study, the commonest reactions were: 1) guilt mentioned by 42%, 2) rejection feelings by 25%, 3) resentment or anger by 32%. 62% of those who experienced guilt, identified their guilt as stemming from their feelings of rejection or resentment. The fathers reacted with longer periods of rejection. Four mothers (13%) admitted feelings of infanticide and

four wanted the child institutionalized. In five cases the resentment was directed towards God, and two couples maintained that it 'permanently shook' their religious beliefs. Several mothers were convinced they had done something wrong in their pregnancy.[20] In another study, 27.8% of the mothers felt it was their fault, and 5.1% blamed the father.[12] The doctor should be particularly aware that such feelings of anger and blame exist and may not be verbalized.

Knowing that the parents are going to be experiencing intense feelings of shock and other strong emotions, the doctor must be careful to be sympathetic and tactful. Doctors must therefore be aware of their own feelings about the child's condition and especially about mental retardation. Roeher (1970) stated that physicians have often seemed to hold negative attitudes towards mental retardation, thus making it impossible to instil positive ones in the family.[19] It is essential that the professional responsible for the welfare of the child show to the parents that they value the child. One researcher stated that professionals who do not feel any value in the infant should delegate the disclosure and earlier interviews to someone who does.[5]

What to Tell the Parents

A. Terminology

A 1976 study found that 65% of the physicians had used the term 'mongolism'. The term 'Down syndrome' was used by 15%, and 16% used the term 'retarded'. Four per cent used other terms including slow muscular development, abnormality, 'something wrong with the glands', brain damage and hydrocephalus. Five (1%) used the term 'mongoloid idiot'. Both the authors of that study and this author feel that while the term 'mongolism' may be more familiar to the parents generally, it conjures up unfortunate stereotypes and racial slurs and therefore should be avoided. The term 'mongoloid idiot' is an outrage. Moreover, while there were several other terms given, parents generally want both information and honesty. The authors suggested using the term 'Down syndrome' but then telling parents that other people may refer to it as 'mongolism'. They also stressed that while correct terminology should be used, the parents must not be allowed to think of a stereotype, but firstly of their child as a human being and an individual.[18]

B. Prognosis

It is impossible to state at birth how any child will develop and this is no less true for a child with Down Syndrome. Parents are often told, however, how they should expect the child to do. In a 1980 study, 47.5% of the parents were told the child would be slow, 35% that the child would be handicapped, 11.3% that he or she would be very retarded and 5% that the child would be no good at all.[12]

Writers emphasize the importance of being neither too optimistic nor too pessimistic. Parents should not be led to believe the child's prognosis is far better than the data indicate or told that he or she may grow out of it or be normal.[7,10] It is necessary that the physician does present the prognosis with an air of realistic hope. It is unreasonable, unscientific and inhumane to give any diagnosis without any hope.[21] The ability of the doctor to do this will depend not only on their knowledge of Down Syndrome, but also on their own personal feelings about the condition. Wunderlich (1977) suggests that it was probably better to avoid making remarks about the child's future since it is impossible to predict and since statements may be prejudiced by personal bias and the parents' own feelings.[25]

C. Information

Parents need to be informed about the condition of Down Syndrome. Authors suggest that the first conversations with the parents should deal with an accurate description of the syndrome.[18,21] Parents frequently complain that very little information was given.[1,3,6,7,18]

Sometimes reading materials have been provided to parents: 15% of parents were given literature in a 1974 study, of which 82% felt it was helpful.[10] Parents often seek out books which frequently contain out-dated information, negative prognoses about survival, or stereotyped descriptions of Down Syndrome. These sources of information are often conflicting and disturbing to the parents.[4] While reading materials may be useful to the parents, the nature of the material and its accuracy and tact should be considered before giving or recommending literature to new parents. Nor should the literature be considered a substitute for talking and discussing the condition with the parent as has happened.[20]

D. Other Parents

Some parents find comfort in knowing that there are others with the same problem; that they are not alone. Meeting with another parent with a child with Down Syndrome can frequently be very helpful to them. In a 1977 study, parents who met with other families with children with Down Syndrome appeared to have made the best adjustment.[5] Despite the benefit of this experience, in a 1974 study, only 17% of the parents said that their informant had suggested that they get in touch with another parent of a child with Down Syndrome. Of those that did contact another parent, 15 out of 16 felt that it had been helpful.[10]

Parent self-help groups do exist to which referrals can be made. Even though not all parents are emotionally ready when first given the diagnosis to contact another parent, the consensus of opinion of many authors is that parents on average benefit from such contact and the offer should be made.[4,5,7,10]

E. Institutionalization

In the past, both the expectations of society and the teacing of medical schools, led to physicians commonly recommending that a child with Down Syndrome be placed in an institution. Previously, some physicians told parents that the child 'would be a menace or a destructive force within the family', and 'would have a negative influence on the siblings'. All these statements are incorrect.[18] In one study in the United States, only a few physicians were making a recommendation for institutionalization. Their statistics showed that 22% of parents told by pediatricians before 1960 had institutionalization recommended, while the figure for after 1970 was only three per cent. They attributed this change to the physicians being better informed of 'the nonavailability, poor quality and high cost of institutionalization' and of a realization of 'the lasting negative effects on the child's development'. Parents in their study commented that had they institutionalized their child, they would have been deprived of the 'joy, enrichment and

satisfaction' that they had experienced raising their child at home.[18] It would seem that doctors are becoming aware that suggesting institutionalization is not appropriate and it is hoped that further improvements may be made in this area.

F. Follow-up Counselling

Telling the parents the initial diagnosis is a beginning. It is not an end. Arrangements must be made for proper after-care such as early infant stimulation programmes and a referral to a self-help group or equivalent. Parents will also want to be informed of what programmes, schools and services are available to them. Moreover, after the initial disclosure of the diagnosis parents will have many questions and feelings that they will need to discuss.[9]

It must be realized that the parents are shocked and much of what is said to them in the first and subsequent interviews may not be understood or remembered. In one study, parents were asked what they remembered from the first interview. Mostly, the answer to this question tended to be of three types: 1) they were so shocked and upset that they recalled little or nothing; 2) they recalled nothing hopeful or positive only what the child would not be able to do or the physical conditions that were associated with the syndrome; 3) they remembered false information or particularly upsetting information such as recommendations for institutionalization or that the child would die early. In this study, only three parents of 32 recalled being told about Down Syndome in detail. Notably these parents were also given written material.[7]

Because parents may remember almost nothing of what they were originally told, because questions will occur to them as they have time to think, and because such issues as chromosomal analysis and genetic counselling are complex and difficult to understand, follow-up consultations are essential. It is hoped that during the original interview with the parents a rapport and process will be established such that on-going counselling and assistance can be given in the years to follow.

Recommendations

Several recommendations can be made based on the findings discussed earlier. They will be summarized below. Explanations for each recommendation can be found in the body of this paper.

1. Tell the parents as soon as the diagnosis is known or highly suspected.
2. Choose a quiet private location.
3. Allow plenty of time — don't seem to be in a hurry to get away.
4. The parents should be told by someone who is knowledgeable about Down Syndrome and mental retardation. This person should value the child as a person and should not allow personal feelings about the condition to interfere. There is no preference for being told by either the obstetrician or pediatrician. Possible resentment is not a reason to exclude the family physician. It is preferable, however, that the parents know the person who tells them.
5. The parents should be told together if at all possible.
6. Parents should be offered the opportunity to allow siblings or other close relatives or friends to be present during some of the discussions of the child's condition.
7. Single parents may wish a close friend or relative present.
8. The baby could be present or the parents should be given access to their child immediately thereafter.
9. Parents should never be falsely reassured that nothing is wrong.
10. They should be told with tact, sympathy and understanding. The informant should be aware of the feelings they are having.
11. They should be reassured that it is not their fault.
12. Encourage parents' questions and allow pauses for them to collect their thoughts, pose questions or air concerns.
13. Proper terminology should be used. Choose words carefully.
14. Do not speak too clinically or technically.
15. Attempts should be made to make the prognosis as up-to-date as possible with an air of realistic hope.
16. Inform the parents about the condition.
17. Good up-to-date written information can be useful.
18. An offer should be made to refer the new parents to other parents or parent self-help groups.
19. Institutionalization should not be mentioned.
20. Follow-up conversations and appointments for further conversations after the mother leaves the hospital should be made.
21. The appropriate medical referrals (such as genetic counselling and referrals to programmes such as early infant stimulation) should also be made.
22. Parents should be told what programmes, schools and services are available to them, especially as the child grows older and these services are needed.

The above recommendations indicate that physicians must be prepared before speaking to the parents. Physicians must be aware of their own prejudices. They must be knowledgeable about many aspects of mental retardation, from the purely clinical aspects to the services and parent groups available. They must be willing to deal with the parents' reactions and questions, and must be willing to take the time. Most importantly, the physicians must blend up-to-date information with sympathy, tact, and caring.□

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PEDIATRICS

Handicapped Neonates: Who Should Decide Treatment?

Yee Ling Chu 8T5

Each year, about 1% of all neonates born in the U.S. are doomed from the moment of their birth.[1] This involves some 30,000 lives and in 1983 the U.S. Department of Health and Human Services set a ruling to ensure

> handicapped newborns no matter how severe the handicaps, receive all possible life sustaining treatment, unless imminent death is considered inevitable or the risks of treatment are prohibitive, as the law must prohibit discrimination on the basis of the handicap.[2]

This rule exists because the law is responsible to all its citizens and must protect everyone. But indiscriminative heroic life sustaining treatment can mean forcing a human being to live a life of pain and suffering. What sort of responsibility is that?

Such fixed rules are irrational because medicine is in constant evolution and, with recent improvements in intensive care and neonatal surgery, babies can now be saved who would have previously died. This implies that life is no longer sacred in the absolute sense and hence maintaining and prolonging it because it represents a value in itself may no longer be valid.[3] Therefore it seems morally wrong to keep a baby alive just for the sake of life. There is also an economic factor, that is, with limited funding and resources, there is not enough money to save everyone, hence a decision with respect to who lives and who does not must be made.

This article explores who should make this decision, and on what criteria.

The people who should be involved in a decision-making are physicians, parents and the public, since the patient in this case is a neonate and cannot give consent.

In the past, the life-death decisions have been made by physicians, and it was not infrequently decided that it would be kinder to let the obviously doomed baby die. The Canadian Association for the Mentally Retarded estimates that every year as many as 1000 infants, comatose and terminally ill patients are terminated purposely.[4] It has also been believed that, no matter what, the final onus is upon the physician responsible for the child.[5] He/she has the technical knowledge and medical foresight no one else has.

Nevertheless, it is wrong to exclude the parents from the decision process because, in the end, it is they who must live with the results of any decision.[2] It was surmised that, when a defective baby was born, the parents were too upset from the initial shock, the anger, denial, grief, guilt and self-blame, and even the wish to "get rid" of the child, to be capable of decision.[6]

The physician, then, must include the parents in his plan of action, for, in such a situation as one parent puts it,

> the physician is incredibly important to the parent(s) and must have concerns for the parents' and siblings' well-being, be receptive to ongoing questions and understand the need for further education concerning the nature of the disease.[7]

The physician must exhibit an attitude of listening, caring and accessibility.[7] With proper counselling and support, the parents will then be able to make informed decisions[8] in the best interest of their child.

Yet this may not be enough. In an editorial in the *New England Journal of Medicine*, it was noted that decisions made between parents and the physicians involved were not exempt from poor judgement. The example given was a case where a Down's Syndrome baby with esophageal atresia was allowed to starve to death.[2] The editorial suggested that other physicians not involved with the case be consulted, and if there were any disagreement, it should come to a hospital committee, preferably one which has parents on it who have gone through the same experience.[9] If the situation remains still unresolved, only then should it be brought to the courts.

This process is a "formula" and does not give any easy answers to a physician confronted with the decision of whether to treat or not to treat. Smith states

> the only fair criterion for deciding appropriate treatment for a given baby is that baby's own welfare and ability to receive love.[10]

This means that the decision making would be subjective and under no control. Stahlman, another doctor, believes in the

> all or nothing approach — as long as there is any reason to treat withhold nothing. When a decision is made that salvageability is impossible, do not prolong the inevitable outcome by halfway measures.[8]

This criterion is at the other extreme and is basically the present philosophy at the Hospital for Sick Children in Toronto. It must be emphasized that the physician has his/her prime responsibility to the patient and it is possible that the patient would not want to lead a life of misery — a life we ourselves would be allowed to reject.[3] Yet is that a reason to let someone die?

The C.M.A. Code of Ethics gives the doctor the right to stop treatment if it is not in the best interest of the patient and is not likely to be of therapeutic value, but the law is not consistent with this view because euthanasia is still classified as murder under the Criminal Code.

Clearly, some guidelines are needed. In a Report from the Law Reform Commission of Canada, it is stated that the right to die with dignity should not be lost because the patient is incapable of expressing wishes and it can be the ultimate kindness to let nature take its course.[3] The Commission recommends better prenatal care, diagnosis and assistance and material support which society should provide for the parents after birth. This is not law, but will carry great weight in Parliament.[4]

In conclusion, the decision must involve parents, physicians and, sometimes, even the courts. No rules are perfect and it is humanly impossible to eliminate all errors. The ruling in the U.S. is too objective because each case is unique with its own special considerations and should be dealt with in that manner. The alternative is too subjective and it is easy to wonder where the killing would stop. The decision, whether to continue or to discontinue a handicapped neonate's life, remains difficult, and if one is still grappling with this thought, then it is a good thing for medicine.□

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Acknowledgement

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Exercise but first Exercise a Little Caution

Not long ago, Jan excelled in many sports, but she especially enjoyed aquatics. A promising career in modelling was also in the works. Most of that changed the day she dove into water too shallow and broke her neck.

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PEDIATRICS

Mother-infant Interaction — Part I: Normal and Handicapped Dyads*

E.H. Keay M.A. 8T5

Introduction

Mother-infant interaction is, as I discovered, a vast topic of great interest, and in attempting to describe it I shall make some assumptions: first, that the mother and child are biological entities and use their senses to communicate by various cues, a word that has rather a broad meaning, and secondly, the cues become endowed with an emotional overlay which quickly becomes organised into larger units and so, difficult to analyse, with the result that the scholarly work is largely an approximation of a small quantifiable aspect. I have also assumed that if the cues are "wrong" in handicapped people then the emotional and behavioural stage will be distorted likewise, unless special measures are taken.

There are some conventions which must be mentioned: the child is described as "he" and the mother as "she", so that identification of the child is made easier. Areas such as institutionalised babies, race, and cultural information have not been discussed. The bibliography is representative only; many further references will be found in any of the cited articles.

Normal Mothers and Babies
A. Cues of the Infant

The baby's physical appearance draws everyone to him: the large head, chubby cheeks and eyes are appealing (Klaus 1975), and by drawing everyone to him, the baby can then express his needs and become a communicative creature. The newborn, of course, cannot speak verbally but does so non-verbally by expressing his various states by yawns, gurgles, grimaces, hand swipes, sucking bouts and startle reactions. These appear to be non-random and instinctive since others respond to them as they are discrete and harmonious with themselves. The actions of the mother and newborn become interlocking (Newson 1977) by the mother responding to these definite cues. These cues may be subtle or obvious, such as that of sleep with its closed eyes, quiet, and regular breathing (Papoušek 1977) act as stimuli for the mother to change her behaviour towards her child (Papoušek 1977). Let us look at some of the cues.

Crying is the earliest cue: the birth cry indicates that the baby is all right (Osofsky 1979) and this single cry becomes separated into a hunger cry, a pain cry and an anger cry. There are pauses in the pain cry which give it an "urgent" quality (Lounsbury 1982). The early cries of pain and hunger are entero-receptive and for the first three or four weeks the child is quite insensitive to external noxious stimuli (Stroufe 1979). The mother is responsive to crying and will try to stop it (Ainsworth, Bell 1969). The cry enables attachment over a middle distance (Osofsky 1979), and an "irritating" quality and pitch of the cry may give clues to a difficult temperament later (Lounsbury 1982). Each mother can identify her own infant's cries (MacFarlane 1975) by experience or predisposition (Sagi 1981). Crying is the beginning stage of a series of steps to vocalisation. Crying alerts the child's care givers that something is amiss, and it is amplified by vowel-like sounds in quiet waking and then by syllabic consonant-vowel clusters repeated in bursts, such a "gah-gah-gah", about the sixth month (Papoušek 1977).

The eye is another important, some might say the most important, cue and like all the cues, it is not independent of the others, for if the child hears a voice he will turn and try to see where the sound is coming from (Rheingold 1961). Thus we might conclude that the cues described in this section are natural reactions of the senses interpreted in a highly structured context. The baby's eyes function after birth by four hours (Osofsky 1979) and are mature by six months so that a baby who has no motor control, can, nevertheless, see things with adult vision (Bateson 1969). Colour and form can be seen by four months and from seven months on, objects attain a constancy and permanence (Cohen 1979). Face perception is not innate: at two months, high contrast facial features are visible, whole configurations by four months and by five months the child can abstract invariant features from faces, such as the same expression seen on different faces (Cohen 1979). The mother instinctively knows the distance at which her baby can focus his eyes, and so both can get the maximum benefit from any interaction (Thoman 1975). This is twenty to twenty-five cm. for the first two or three weeks, and she tries to stay centred in her child's visual field, with her eyes in the same plane as his (Papoušek 1977). The periods of steady contact vary according to the infant's state, and help the mother decide if she is providing not enough or too much stimuli to her child (Papoušek 1977). Her baby will turn away if there is too much (Exline 1982, Papoušek 1977). A fast rate of blinking indicates high arousal (Exline 1982).

The cues described briefly above serve one purpose at first in the newborn: to ensure that he is protected, warm, and fed. This assumes that the mother responds to her infant's cries and uses various methods to comfort him and, soon, she learns to distinguish between the pain cry and the hunger cry (Wolff 1969). The degree of a mother's sensitivity to her infant's signals is an important influence of the infant's attachment to her (Ainsworth, Bell 1969). Difficulties in feeding may be related to the type of medications the mother had in the prenatal period, as some, such as meperidine, thiopental,

*The bibliography for parts 1 and 2 will appear at the end of part 2, because of its length.

lidocaine and mepivacaine, have been shown to lessen feeding, the amount of food consumed and the rate and vigour of the sucks (Brackbill 1979). These may be related to difficulties such as a long labour and its effects on the baby's state at birth (Dunn 1975). The ease of early feeding also depends on the shape of the mother's breast, if she is breast feeding. This will be described below. It also depends on her anxiety level about breast feeding (Sostek 1982).

The feeding of the baby changes from birth, when the corners of the mouth are shut, the eyes closed and the pressure even throughout the mouth. Instinctive sucking occurs at regular intervals, but it is stopped by a new stimulus, while the non-nutritive sucking indicates a lowered arousal level. By the fourth week, the corners of the mouth are open, the pressure is at the rear of the mouth, and the baby can look around and pause while feeding, as well as adapting to the different flows of milk (Bruner 1969). Sucking occurs in a burst-pause pattern which depends in part on the consistency of the milk: breast milk is more watery than formula, and so the baby must suck and swallow faster for two or three minutes, the burst of nutritive sucking in the newborn (Johnson 1975). The pause is a period for interaction. There is no correlation between burst and pauses (Kaye 1977). He also has extralingual tastebuds on the epithelium of the additus of the larnyx which may act to stimulate sucking, especially when the pressure of the nipple is at the rear of the mouth (Johnson 1975). The non-nutritive sucking is stereotyped but plastic by four weeks, while the nutritive is adaptable immediately after birth so that child can regulate his food intake by both feeding and "conversing" with his mother (Crook 1979). Feeding is the earliest example of the mother and child "taking turns" (Kaye 1977). If the mother is not in close contact with her child while nursing, she won't be later (Schaller 1982). This may affect attachment, especially if the mother is normally naturally a close person.

The next group of cues are based on the mouth and the eyes and can be loosely grouped under the term "face". The human face is a complex of interesting, responsive stimuli (Rheingold 1961). The baby can recognise his mother's face at fourteen days (MacFarlane 1975).

The smile is an important cue for the mother's attachment to her child, and it is one which changes since the smile at three months is not the same as a smile at nine months. It seems to be based on earlier cues since the eye-to-eye contact at six weeks becomes the eye-to-eye contact with social smiles at around eight weeks with a corresponding lessening of interest in inanimate objects (Fogel 1982). At this time, from eight to twelve weeks, the child learns to smile at static visual stimuli and this requires a great cognitive effort on the part of the child (Stroufe 1979). In the younger infant, the smile orients him to noise stimuli, followed by release behaviour such as gazing away (Stroufe 1979). The early smiles indicate a high state of arousal which the child must learn to assimilate and tolerate. His mother helps him do this (Fogel 1982). Wolff (Wolff 1983) has traced how the smile changes in the first two months from a spontaneous to a selective response. In the first week, the smile may be a spontaneous discharge after the eyes close, or after the child hears a noise. By the second week, the child will smile at a voice, and will smile with his whole face by wrinkling the eyes and by the third week, a high-pitched voice will elicit it consistently, and the child will smile when fully awake and tracking an object. In the first month, the child smiles at eye-to-eye contact and the response becomes more predictable and repeatable, especially with the voice. By two months, the baby will smile and gurgle while exploring the environment, and won't smile when he tastes something himself. Like the other cues, smiling changes from being a physiological response to a psychological one (Wolff 1963), from endogenous to exogenous (Sameroff 1978).

Smiling has an important place in the interaction between the mother and child since it shows an intensity of affect at the beginning of an interaction when the child gazes and smiles at the mother as he is in a high state of arousal, as noted above, and then must withdraw by gazing away because he cannot regulate his arousal (Fogel 1982). Another form of tension release is laughter (Fogel 1982) in which the young infant (four weeks) laughs when there is conflicting emotion (Wolff 1969). There are probably other cues which are used by the mother as she tries to know her infant. One example is that of the baby's hands which help her decide whether to stimulate her baby more or less. In the infant passing from waking to sleep the hands are first raised and partly stretched to the mother, fingers moving and palms open, then they drop slowly by baby's side, while closed fists indicate fatique or distress (Papoušek 1977, Hannan 1982). At three weeks, the baby will make cycling movements with his limbs when his mother approaches (Brazelton 1975).

Just as there are cues the baby uses to draw his mother's attention to him, so there are factors within her to ensure that she responds with certain cues. The baby cannot cling so he depends on the mother being motivated to provide his need such as by the physiology of her pregnancy or auditory or kinesthetic intrauterine cues (Brazelton 1975) and the stimulation of her infant (Biological, 1969). Each mother has her own smell, and this is important to the baby so he can locate his food source and recognise it. He can recognise her on this basis by six days (MacFarlane 1975), and will turn his head to her breast before his cheek touches and stimulates the rooting reflex (MacFarlane 1975). The rooting reflex places the baby's gaze in the median ventral line so that he looks at the mother's face (Blannet 1961). More mothers carry their babies on the left side so that the baby looks as his mother on his right (de Chateau 1980). The baby naturally turns his head to the right in most cases, and this elicits holding preferences by the mother (Bundy 1979). The reason for this is unclear, it may be motor (Liederman 1980 and rebuttals). The feeding and sucking mentioned above follow the rooting reflex, and the success or failure of breast feeding (the only kind considered in this paper) depends largely on the shape of the breast. If the nipple fits easily in the mouth, then there is a stimulus in the newborn to feed, while there is an "apathy" response if the breast won't go in at the first feed. If the baby's lip pushes on his nose while feeding at the breast, the baby will suffer anoxia, the feed becomes difficult and the mother feels rejected by the baby (Gunther 1961). While feeding at the breast the baby learn to pick up his head (Gunther 1961) and so gets extra visual stimulation.

B. Cues of the Mother

Before breast feeding at birth, by six minutes (Klaus 1975) the mother touches the infant in a certain way so that there

are reflexes, such as the rooting reflex, elicited in response. The touching has been described as touching the limbs of her newborn with the tips of the fingers and then moving her hands so that the palms touch the trunk (Klaus 1975). She will hold her baby on her ventral surface (Blannet 1961), she will speak in a high pitched voice and stroke her baby after touching him as described above. She will look at her baby *en face*, and then will feel close to him. Eye contact may be a release for maternal behaviour (Klaus 1975) though it might be agreed that there are so many events happening at this time, this is one of many. The mother will place the child in his range of vision, use a slow modulation in speaking and may move her baby's limbs (Papoušek 1975). The mother will try to integrate the newborn into the family by commenting on resemblances to family members (Osofsky 1979). If her baby cries, the mother may try to lessen it by rocking at a rate of sixty to seventy cycles per minute, at this frequency the rate of the baby's respiration changes and the heart rate drops (Discussion 1969).

The mother's face is as important to her baby as his is to her. The face is stimulating since it is made up of a stable triangle of the eyes and nose, with the changeable mouth below and eyebrows above (Papoušek 1975). The mother's face is considered an elemental cue for her baby and it is used as a measure of the baby's development. When the child looks at his mother's unresponsive face, he tries to elicit a response; at three weeks, his movements are jerky and he averts his face trying to draw her into an interaction and then, when the face responds, the baby looks puzzled and then moves his limbs cyclically (Brazelton 1975). At one year, the response to the still face is related to the child's attachment to his mother (Tronick 1982). The response to the still face depends on how much this deviates from the mother's usual experiences with her infant (Stoller, 1982).

C. Prenatal and Perinatal Influences

The attachment of a mother to her infant depends on many factors either within the mother or as part of the mother's surroundings. Certain of these, such as handicaps of the mother are alluded to elsewhere, but here will be discussed things that affect most normal mothers. The age of the mother is important, especially with teenage mothers who play fewer games with their babies (Field 1980). The mother's life before the birth has effects on the relationship. Maternal self-concept, self-esteem and recollection are related to the quality of attachment (Tronick 1982). Her relationship with her mother, her husband, her culture and preparation for pregnancy (de Chateau 1980) as well her psychological state at the time of delivery are important (Prechtl 1983). This last point has been emphasised elsewhere in the discussion of handicapped babies. Anxiety and depression will bring about fewer interactions when the baby is born (Packer 1979). The mother may be anxious about breast feeding (Sostek 1982). This may be detected ante natally, as will be the indentification of mothers who come from a disrupted family, especially with long separations, divorce or death(s) of parent(s). (Hall 1979). They too have poor interaction with their children. Whether the baby was planned or not affects the mother (Kennell 1975), so does exhaustion, marriage conflicts and an ill child (Papoušek 1975). The mother's temperament is important. If she has a slow tempo, the child will be slow too (Dunn 1979). All of the above will affect the mother's fantasizing about her baby (Osofsky 1979), a process which may be jarred by the birth of a handicapped child as noted elsewhere. The mother's socioeconomic state will also affect her relationship with her child. If she comes from a working class background with a disrupted family she will have difficulty (Hall 1979). Such mothers tend to have babies of lower birth weight who are handled less and who may have difficult temperaments (Field 1980). They have little control over their children and are more physically stimulating whereas middle class parents use auditory and visual stimulation with more face-to-face positions (Osofsky 1979). The middle-class mother's responses to vocalisation in the child is vocalisation and the cry prompted a touch in the middle class other while the lower class mothers used touching for infant vocalisation and vocalisation for crying (Osofsky 1979). The middle and upper class mothers have more time for their babies and know more about stimulating them (Leiderman 1975) with consequent increases in vocalisation later (Osofsky 1979). Because there are such clear differences in behaviour this has been cited (Leiderman 1975) as evidence that the ethological theory does not hold, that is, a species specific behaviour uninfluenced by prior experience and culture.

Primiparae may have different problems of attachment with their babies. They tend to have more drugs because of their longer labour and this may or may not be a factor (Braekbill 1979). The ability to respond to her child's cues depends both on the mother's personal style and on her experience with babies: primiparae go to the crying child more often since she does not yet know what the different cries mean (Wolff 1969, Saunders 1969). When primiparae were given extra contact with their babies, they acted more like multiparae so that their behaviour was more synchronous with that of their children (de Chateau 1980), and a primipara from a disrupted working class background may need more help still (Hall 1979). There is some dispute as to whether multiparae infants get less stimulation than primiparae infants, this may not be the case because the sibs of a newborn of a multipara may provide as such stimulation (Bates 1982) although of a different sort, for a six month old infant.

The child of a primipara, especially if a boy, may have a mother who expects more gratification from him (Leiderman 1975) and so may have a more demanding mother. This brings us to the next, and last quality to be discussed in this paper, that of the sex of the infact and how it affects attachment. This may be by the genetics inherent in the sex of a child, or in the cultural expectations placed on him. Boys are harder to care for and respond better to visual stimuli while girls respond better by auditory stimuli (Friedman 1981, Osofsky 1979). Boys at three months of age are touched more, and their vocalisation prompts the mother to hold him *or* talk, but mothers looked at and talked to girls more, and their vocalisations prompt the mother to hold them *and* talk to them (Pawlby 1980). At twenty-seven months, the girls of mothers who interacted poorly vocalised less well than the boys (Pawlby 1970). The father may be an influence on the boys. Baby boys get more affectionate behaviour because they are valued more highly in a particular society (Leiderman 1975, Packer 1979), provided that it is true of that culture. Boys get more breast feeding and are burped more and so get extra contact (de Chateau 1980). Girls may cry more (Stroller

1982), even girls of one week old will cry more when naked than boys (Wolff 1969) but the boy's cry may be more irritating (Crockenkerg 1982). If there are differences in early interaction, it is to be expected that there are differences in older children. This will be shown briefly in the following example. Girls show anxiety to strangers earlier and more intensely than boys (Bateson 1969 D). Boys who have responsive mothers at ten months will show interest in strangers, but girls must be "pushed" at ten months (Martin 1981). However, the sex of the infant may not be a factor if the age and social backgrounds of the infants is taken into account (Bates 1982).

D. Handicapped Dyads
I. Child

The handicapped child or mother is at a disadvantage in forming a solid bond either because the cues are not present, as in some physical handicaps, or are not responded to by replies that are instinctively or socially referable. For example, handicapped children smile less, especially Down's Syndrome babies, than normal babies before the end of the first year, both groups of babies smile less, but the normal babies do because they begin to differentiate between object and person. Handicapped babies may begin to smile more by three years, but the mothers don't respond because this is later than babies normally smile and they smile in return (Brooks-Gunn 1982 D). Children who have a broader range of behaviour are more advantaged than those who do not have one (Kopp 1979).

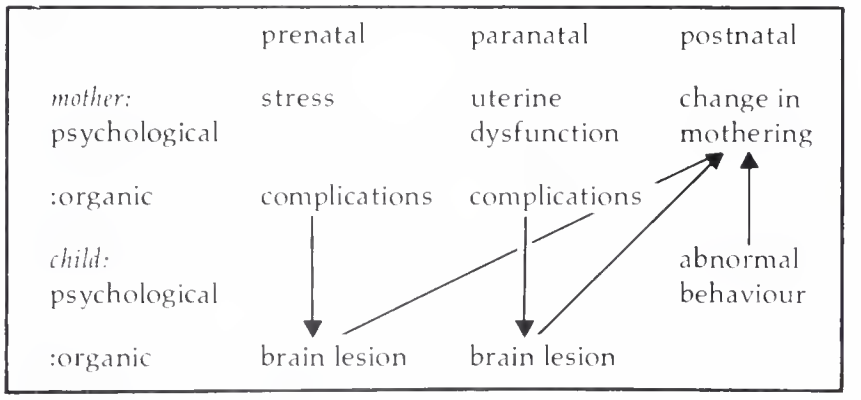
The narrow range of optimal stimuli is set out by Field as follows: (Field 1982 a).

Self control over arousal (ego)		
	high control	low control
high arousal	stability of arousal level	labile
	high or peak experience	defensive withdrawal
moderate arousal	regular cycling of arousal	unpredictable fluctuation
	contentment, confidence, security	anxiety, ambivalence, insecurity

One can see that children who have low control and high arousal will have a narrow range of optimal arousal. The narrow range may be revealed by less eye contract, gaze aversion, an odd cry or fewer arousal states which may even be reduced to two, such as a sleep-cry cycle (Osofsky 1979). This places many demands on the mother as she must change her level of interaction with the child so that he get stimulation suitable to his ability to assimilate it and lessen periods of negative, affects which tend to predominate in handicapped children (Brooks-Gunn 1982) and which will handicap learning later. One must not underestimate the effect of having such a child has on the mother, who now must cope with her newborn while mourning her idealised child. The baby must fit her fantasy (Klaus 1975 D). The birth of a handicapped child brings a feeling of first shock, panic, helplesness, anger, guilt and a final feeling of "do something!". The mother goes through the grief reaction which may be considered an index of the degree of energy which can be channeled for the child's help (Als 1980).

The discussion of attachment of the handicapped child and his mother, or vice versa, intends not to be exhaustive, but, like other parts of this paper, to give a brief outline of some of the more current research in the area. Although there is overlap between physical and mental damage in handicapped children, I shall examine first those children who principal handicap is from brain damage. Small babies who are handicapped in this way have abnormal cries (Scherer 1982) which are very shrill and piercing so that the mother may want to avoid handling the child altogether. This cry is heard by the first week (Wolff 1969). Children with minimal brain damage, as revealed by abnormal reflexes (Prechtl 1961) may be hyperexcitable when there can be little interaction because they have a very low threshold, or hypoexcitable (Prechtl 1961) where there is little interaction as well because the high threshold necessitates a high degree of effort by a mother who may not be willing or able to do this. Such an apathetic newborn will display little exploratory activity, and will not be appealing to the care giver, who may eventually give up trying to stimulate her child, since her efforts are not adapted to the infant's abilities to respond (Kalveboer 1979). The mothers ability to help her child depends on her own psyche before and at the time of delivery.

This is set out by Prechtl for minimal brain damage, thus: (Prechtl 1963).



Autistic babies don't cry, and are therefore thought of as "good children". They don't demand food and can be left alone without protest. The mother must decide whether or not her child has eaten enough because the child can't signal with the appropriate cues and interactional feeding behaviour. The mother also tends to smile less at her child (Biological 1969). Another form of autism will be discussed below.

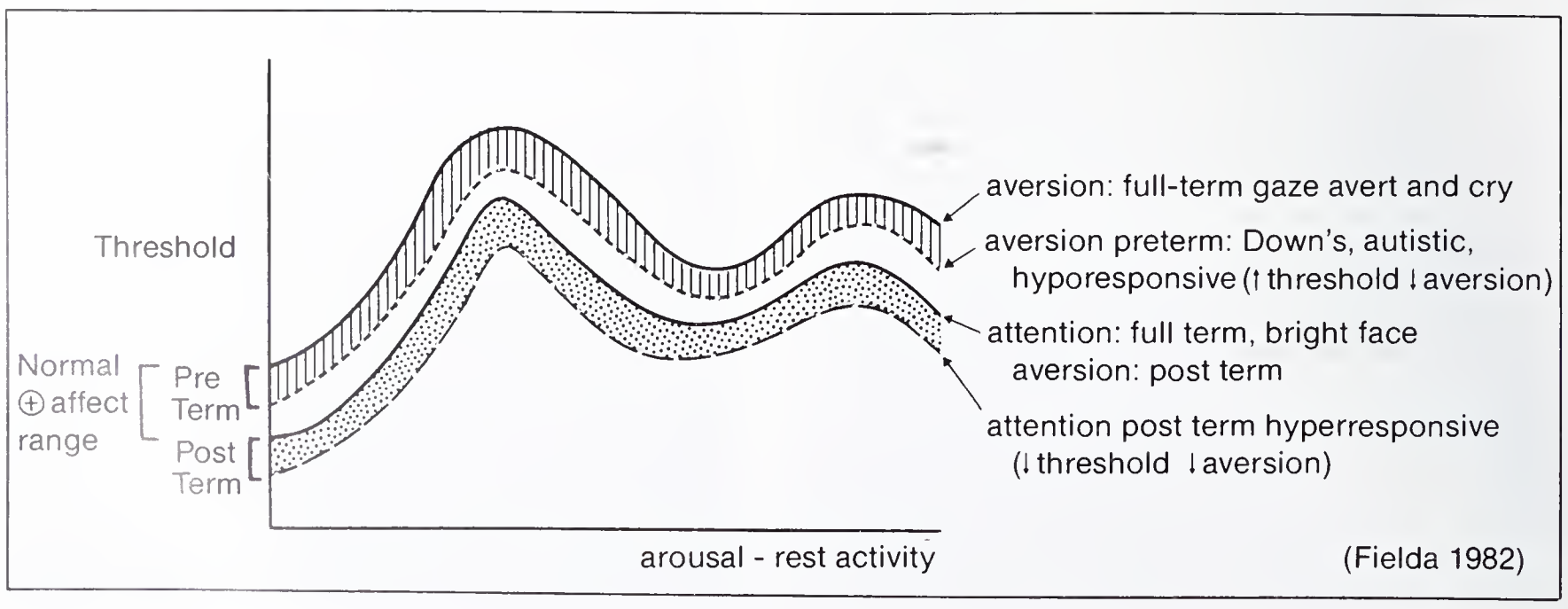
Down's syndrome is recognisable at birth, and so, theoretically, special methods can be devised so that the infant is kept within the arousal range. The developmental lags begin to appear by the end of the first year (Kopp 1979). They can participate in prelinguistic communication with their mothers, but they do not get the maximum benefit from them. They do not initiate many sequences, nor are they given much opportunity to do so by their mothers (Jones 1979). Even the cry of a Down's syndrome baby has a less "urgent" quality about it than that of a normal full-term or an ill full-term, (Zeskind 1980) and so the mother may not respond as quickly. There is less eye contact but long periods of vocalisation: both of these make it difficult for the mother to establish contact and she responds with short words such as "mm" or "yes" (Jones 1977). These children are less vocally

responsive as well (Brooks-Gunn 1982). The mother may tend to direct the play of older (eight to twenty-four months, chronological age), children, whereas she should be taking cues from the child so that he can get a sense of competence (Jones 1980). One might say that the mothers are working "too hard" at the dialogue (Jones 1979). Down's syndrome babies smile less (Kopp 1979, Brooks-Gunn 1982). So do the mothers (Brooks-Gunn 1982). In the case of the Down's syndrome babies, there is a lessening of cues on the part of the baby who is hypotonic, and a corresponding increase on the part of the mother, so that there is an unbalanced interaction to the detriment of the child.

Physically handicapped babies that is, those whose main impairment does not involve the brain, are lacking in one or more of the cues, and others adapt correspondingly. For example, a blind baby "freezes" as his mother approaches. This is regarded as a negative response by the mother unless she understands that it is a "good" response because the baby is trying to listen to her approach (Jones 1980). There is no eye contact with blind babies and the mother may have trouble accepting her child. One child who had anophthalmos was regarded as a "person" by his mother only when he was given glass eyes at the age of eighteen months (Klaus 1975 D). Blind babies smile, however, and this is considered evidence that it is genetic cue (Biological 1969). Gils has compared a blind infant-mother pair with a normal sighted pair (Gils 1980). In the normal child, the mother elicits play at twenty-five days, but by sixty-eight days, the infant "controls" the play. By ninety-two days, there is a relaxed availability of each after play with non-monitoring. In the blind infant, there is little mobility at ten days and a low level of interaction by twenty-five days. By sixty days, there is a play dialogue with the mother in "command" and by four and one-half months there is her relaxed availability. Thus one can see, that for play sequences at least, there is a delay when an important sense and cue are missing, and the mother must recognise what the child wants when he cannot speak or see.

Thalidomide-affected babies place the mother in a cognitive dissonance vis à vis her child and the defect. Décarie (Décarie 1969) shows that most tests of intellectual development in older infants and children use fine prehension. The Pagetian intelligence also needs prehension as part of the co-ordination of sucking, vision and Kinesthesia, since without prehension there is no object permanence. The ethnological interpretation of Bowlby uses clinging and following as an indication of the child's tie to his mother. Decarie has shown, depending on the degree of handicap, that thalidomide babies could achieve object permanence at a later age (twenty-four to thirty-one months), than normals, provided their hands could meet in midline and grasp part of their heads, and most could cling if not follow. Here again the child adopts his other senses to compensate and so becomes socialised at a slower rate than non-handicapped.

Another "handicap" is prematurity, which in this paper won't be accompanied by any neurological or physical deficit, and here will be most of the discussion of separation of the mother and child in the incubator, even through the full term baby may be in one as well. The premature moves less than the foetus of the same age who has more self-stimulation floating in the womb. (Discussion 1969). Thus he is depreived of the full-term's prenatal stimulation and intrauterine auditory and kinesthetic cues (Brazelton 1975) mentioned above. The normal sequence of touching the newborn, the fingertips on limbs, palms on truck, then eye to eye contact, as discussed above, occurs with prematures as well but the rate is slower (Klaus 1975, de Chateau 1980). This sequence presumably occurs if the baby does not have to be rushed to an incubator. If the baby must be separated, this is harmful to the mother's confidence in mothering and may show itself later as diminished committment to her infant and by a higher divorce rate (Packer 1979, Leiderman 1975). The mother must go home alone and she is not preoccupied with her baby (Richards 1979). When the baby comes home, there will be less face-to-face contact, less kissing and hugging (Richards 1979) even though the baby needs more touching (Leiderman 1975). The infant will take longer to get into regular cycles of waking, sleeping and feeding and it is during this period that the mother must get a sense of responsibility for her child. Otherwise the separation, which does not normally leave a permanent effect (Richards 1979), may be damaging. The length of separation is probably important. The four month old premature (four months from the full-term date) shows fewer smiles, more negative affect, along with an increased heart rate which may show increased stress (Field 1982 a). Despite the fact that they are more fretful and play less, nevertheless, they looked at objects and the envir-



onment more than normal babies. This difference disappeared by fourteen months (Crawford 1982). The mother should imitate the infant so there is no arousal overload since these babies have even more difficulty than normal ones in regulating arousal. The pre-term baby has a higher threshold but a narrower range of behaviour, while the post term baby has a lower threshold and an equally narrow range (Field 1982a). She draws a model to illustrate this, as well as other handicaps such as Down's syndrome.

By eight months, the premature is behind the full term baby more than he is at any other age (Goldberg 1980) because this may be the cumulation of the difficult period from five to nine months in normal babies, since he is less responsive and alert to caregivers and is poorly adapted as a partner to the mother so that she must give more care to her infant (Goldberg 1980).

2. Mother

The mother may have a handicap which hampers her efforts to look after her normal child. (Handicapped mothers and handicapped babies will not be discussed). For example, the mother may be blind. The eyes are important to a normal child: if a normal child is shown a face with no eye spots, he smiles vaguely or looks doubtful since the familiar is distorted (Wolff 1969). When the mother has been blind since birth, she has a "masked face" which is upsetting to her baby who is preset for visual input and face-to-face displays. The child does not look at her mother so she must adapt so that their interaction is in synchrony. A mother who is blinded at an older age will "talk with her face", and the child will look at her (Brazleton 1975) so that less adaptation is necessary.

The mother may show ambivalence to her baby, whether he be normal or handicapped, and this may produce either a handicapped toddler or a non-progressing handicapped baby respectively. The mother's attitude is revealed by whether she calls the baby "it", complains about his physical characteristics or sex, and does not look at him (Osofsky 1979). Handicapped babies often have difficult temperaments (Brooks-Gunn 1982) which are punished by abuse (Korner 1979), while a difficult temperament of the mother may produce an autistic toddler (Massie 1981). This can be caused by maternal: dimished eye contact, holding and physical contact, or too much of one parent interfering with attachment behaviour by the other, depression, absence by illness or aberrant responses such as the baby's cry being interpreted as hate (Massie 1980). In all of these, there was interruption of the normal mother-child interaction and these stress how important each of these, and others, is in the attachment of mother to her child and the subsequent development of the child.

E. Suggestions

What can be done to help mothers care for their babies? Mothers should imitate the expressions and vocalisations of hyper-responsive and hyporesponsive infants (Field 1982) so that they regulate their own arousal level and get a sense of control or participation in an interaction. The infant must get feedback that his signals are received (Thoman 1986). Prematures need extra touching (Leiderman 1975). In each of these cases the mother would be helped by being video taped while interacting with her baby, the result analysed and the mother counselled. The behaviour on the video would have to be considered not as representative of normal interaction, and would thus pick out gross errors only. Most people do not act naturally while being filmed.

Hospitals can help easing later difficulties by changing some of their practices. Prematures in incubators can receive extra stimulation with coloured sheets and small mobiles (Discussion 1969). They can allow more handling of the newborn during the first hour and day when he is awake for interaction (Packer 1979) and thereafter. In intensive care, babies receive about *eight minutes* of contact per hour and the contact is usually painful, while in post-intensive care the contact is caretaking and soothing (Marton 1980). They can wash the mothers breasts but not use creams so that the baby can get to know his mother's smell (MacFarlane 1975). In other words, they should be an unobtrusive as possible provided that the baby's and mother's medical states permit! □

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COMPUTERS IN MEDICINE

The Future is Now, Part II: Computers and the Medical Office

Paul H. Marks 8T6 and Paul E. Rosen*

Physicians have become increasingly interested in computerizing their offices. The physician requires some knowledge of computer systems, and answers to the questions of what a computer system can accomplish; what equipment is needed; what attitudes exist toward computers; and how to go about buying a system. A glossary of terms is included.

Introduction: The Environment

There are significant problems in medical care delivery systems in this country: skyrocketing costs, lowering of service quality, the financial bind the patient finds himself in, etc. These are the symptoms of a people-system. The more personal service required, the less people there are prepared to perform them competently and therefore, a cost-push inflation results. The usual solutions to the equivalent situation in industry is increased productivity through mechanization, the route often taken by manufacturing operations.[1]

Medicine is different. The process through which the ill person is transformed into the healthy person, involves a very important component: the relationship between the health care personnel and the patient. This human interaction will always play a vital role in the healing process. The other aspects of medicine, such as the collection of data with factual, measurable physical and psychological parameters, and the management of the basic financial and organizational operations of the office, clinic, or hospital in which health care is performed, are suitable for mechanization.

The computer can increase the efficiency of health care, and reduce the excessive costs by increasing cash flow, reducing the cost of the administrative workload, and eliminating many routine functions that are now necessary in today's medical office.[2]

The Information System

The growth of the small computer market is staggering. Just in the small ($1,000 to $5,000) microcomputer market alone, it is estimated that in 1983, Commodore will have sold up to 2,500,000 units, and in 1984, that IBM will sell 800,000 Personal Computers ("PC's") and Apple will have sales of 600,000.[3,4] This explosion has helped to precipitate the recent growth in the number of computerized medical offices by increasing the capability of the hardware and availability of good software, while decreasing the price of those components.[5] With this flurry of activity on the professional front, and the bombardment by the media about computers at home, many people are left intimidated by their lack of knowledge of computer systems. What exactly are computer information systems, and what are their components?

An information system is a set of organized components designed to produce data suitable for making decisions. The system has four major components: input, programs ("software", processor ("hardware"), and output. The relationship between these components is shown in Figure 1.

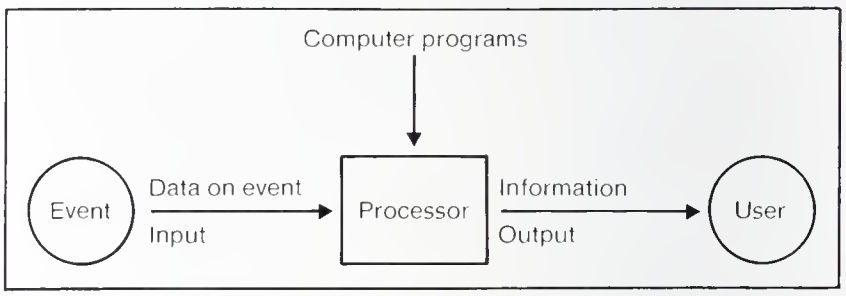

Figure 1 Relationship of components in a computer system

Using the technology presently available, a task such as billing for an office visit is entered into the computer as input. Data such as patient name, address, date, etc., is entered by using a keyboard similar to a typewriter. The information is translated into language understood by the computer. The processor (central processing unit or CPU) deals with this information in accordance with the instructions coded in the program. Finally, usable information is displayed on a monitor or screen as output. Alternatively, the output may be a printed OHIP card, invoice or statement. Presently, these systems are capable of transmitting the data to other locations such as the OHIP office via telephone.

If the physician is to employ a computerized information system, similar to the one outlined above, it is imperative that present and future informational needs be outlined.

System Overview: What can it do for me?

The physician who is a novice in computer technology is often overwhelmed by jargon and confused by overeager salesmen. A prospective user may ask: "Why should I get a computer for my office? What can I realistically expect it to do?"

There are three main reasons for a physician to purchase a computer system. These are for financial, administrative, and clinical functions.[6]

*Mr. Paul E. Rosen is a medical specialty representative for a computer consulting and marketing firm.

1. Financial

The primary reason most physicians purchase a computer today is to handle financial functions. The system can speed the processing of billing information and receipts for payments. Computers can quickly produce financial statements and OHIP or WCB cards. It can list billings, payments, and overdue accounts. It can help track supplies, and can produce order lists when supplies are low. Productivity reports can be generated. Payrolls can be automated. In addition, a computer reduces the percentage of rejected OHIP cards and decreases the time between billing and payment (from 10 days with computer-printed cards to 60 days with magnetic media). Finally, equipment can be written off for tax purposes at rates of 30% for hardware and systems software and 100% for application software.[7]

2. Administrative

Information on the financial aspects of a practice can aid in making administrative decisions. A computer can perform functions such as scheduling of office appointments and hospital visits, tracking of hospital patients, and production of repeat prescriptions and labels. Word processing can increase output up to four times. A word processor can be used to type letters and research papers, and also to print patient data forms, personalized patient information sheets, and mailing labels.

3. Clinical

Clinical advantages of a computer system are less tangible, but are in a state of rapid development. Research data can be collected very rapidly, with increased accuracy and utility. Individual patient data is quickly and easily retrieved. Medical networks, such as MEDLINE database on the Knowledge Index network or N.L.M.'s MEDLARS II, provide up-to-date information on such topics as drug interactions, research statistics, new procedures, and journal articles.[8] Specialized clinical applications for the computer in orthopedics can, for example, calculate the stress on a knee replacement.

4. Other Considerations

Up to 35 percent of billings in provinces that accept computerized billings are now performed by computer, and the number of medical offices becoming computerized is rapidly rising.[9] The OMA has taken an active role in making the new technology available. It is likely that most offices will be assisted by computers. Can individual doctors afford to ignore the new technology? Efforts are now under way to educate medical students about computers so that they will not be disadvantaged among professionals.[10] Since computers are here to stay, the question is not "if", but "when" to implement computerization.

Computers have a number of possible disadvantages. Among these are:

a. Security problems

The maintenance of confidentiality is a vital factor in the acceptance of any medical information system. Much has been made of the "computer bandits" who steal money and information from private computer records. This problem exists only for those who store their information on such data bases, and not, at present, for medical offices. With medical office systems, there exists the potential of non-medical personnel searching through patient information.[11] This is successfully dealt with by using password entry and by leaving the computer off while it is unattended.

b. Loss of information

Information may be lost due to power outages, system failures, voltage fluctuations, disk damage, dust or static electricity. Entire patient files may have to be reconstructed and entered unless precautions are taken. The simple solution is to create backup copies of essential files.

c. Decreased efficiency

There is a possibility of a computer system actually decreasing the efficiency of an office. This may occur temporarily during the primary stages of implementation of a computer system.[12,13] Unfamiliarity with the system or the procedures may confuse the staff. Waiting for access to the terminal, or making frequent changes in printed forms may decrease productivity and result in frustration with the computer. As proficiency is gained, efficiency levels rise beyond their former level.

d. Low staff acceptance

Resistance occurs for many reasons not only in the office staff, but also in the physician. Fear of the unknown plays a role in personnel not acquainted with computers and technology. Reluctance to learn the new system is also significant. In the past, software was often not easy to use. The remedy for this situation lies in the purchase of systems designed for those not literate in computers. Formation of realistic attitudes of both the physician and the staff toward the computer is esential.

e. Cost

There are many financial benefits to be gained from a computer system. There is a cost for those benefits. Computer capability has expanded and prices have been reduced. It is unreasonable to assume that a computer designed for home use will be practical for use in the office. A realistic figure for a turnkey medical office system is approximately $10,000, with a breakdown of $7,000 for hardware and $3,000 for software.[14] Less expensive systems are suspicious. Costs can be reduced by purchase and sharing of a multiple doctor or clinic system. Tax advantages were mentioned earlier.

Transmission of Data: Sending Information to OHIP

The type of data transmission that is most vital to the majority of Ontario doctors is between offices and the OHIP billing centre. Cards can be prepared rapidly by using a computer and printer. Acceptance of magnetic data storage is of

interest to doctors. By sending in a floppy disk or a tape containing the month's transactions, a physician receives payment up to sixty days earlier, and a disk is returned with the transactions reconciled and the rejects flagged. At present, all tape, and only some floppy disk media are accepted by OHIP.

Billing and reconciliation may soon be accomplished by modem. A modem is a component that permits direct transmission of informtion between computers via a telephone line. In this way, data could be sent by telephone wire in a matter of minutes, and reconciliation returned almost instantaneously. Payment would then be made in a matter of days. Negotiations with OHIP are in progress at present.

Present Trends and Attitudes

A recent survey article suggests that there is little uniformity between various medical office computer systems.[15] Systems range from home-made programs on small home computers to sophisticated custom-designed programs on minicomputers. Price tags span a low of $3,000 to a high of $65,000. It is estimated that 400 medical office systems presently operate in Ontario. Growing interest is displayed by the growth in the number of medical turnkey vendors, and by the recent OMA sponsored seminar and presentation of a "bulk" purchase proposal. Most physicians are considering the feasibility of computer office automation.

Single office and multi-user clinic installations represent the two major trends. Most popular is a turnkey system that runs on a microcomputer and handles patient data, billing, and appointment scheduling. Additional programs, such as financial, word processing, spreadsheet, and research data packages, are available. Physician groups and clinics are inclined toward a minicomputer with multiple terminals. The central unit processes information from all the clinic terminals. These systems usually provide specialized software with demographic, search, hospital scheduling, detailed financial and practice management functions.

Increased interest is due to improved quality and capability of both hardware and software, at declining costs. In addition, systems have become increasingly user friendly (i.e. require less computer knowledge).

Guide to Buying a System

Check List for Comparing Systems[16]

Computer:
- How many installations?
- 8-bit or 16-bit?
- Can it take extra memory boards?
- If so, is it a standard bus?
- Warranty period?
- Availability of spare parts?
- Susceptible to voltage fluctuations?

VDU (Visual display unit):
- Clarity and colour of type face?
- Any flickering?
- Keyboard feels comfortable?
- Pre-programmable keys?
- Detachable keyboard?

Printer:
- Quality of type face?
- Speed?
- Widths of paper it can handle?

Storage:
- Hard or floppy discs?
- Size of discs (either type)?
- Are they the type of discs that the system was originally designed for?

Expandability:
- Can it change from floppy to hard disc?
- Capacity for extra VDU's?
- Can it take 2 floppy disc drives?
- Can it take extra printers?

Performance:
- Speed of access screen change?
- Quantity of data on screen?
- Presentation of data on screen and printout?

Software:
- Quantity of data per patient?
- Quality of presentation of data?
- Are changes possible to suit your individual needs?
- Ease of entry of data?
- Does it use a "menu" to get from one part of the system to another?
- If so, how easy is it to understand and use?
- Are the screen presentations geared to easy use by unskilled personnel?
- Extent that input is preloaded?
- Quality and extent of analysis of data?
- Analyses against whole "fields" or within "fields"?
- What security system is used to protect confidentiality?
- How effective does it appear to be?

Company:
- How long in business?
- Any systems sold?
- If so, what configuration are they?
- Exclusively medical?
- Maintenance contracts?
- Installation arrangements?
- General impression of company?

General:
- Costing for each phase item?
- General impression of system?

The Future

What might the future hold for medical office computer systems? Some suggestions are:

1. Computers will be more convenient for access, more compact, and more compatible with computer-related equipment manufactured by a wide range of vendors.
2. Computers will be simpler to use. For example, they will be conversational in mode, making it easier for non-technical personnel to communicate with the computer system.
3. Data will be transmitted by satellite; intercontinental teleconferences will be routine.
4. Medical networks will develop and expand to accommodate many more functions.

5. Medical education for undergraduate, graduate and post-graduate students will be done by computer.[18]
6. Integration of office, clinic, hospital, pharmaceutical, and laboratory databases.
7. Computer simulation will result in increased understanding of body functions and better prediction of medical procedures.
8. Artificial intelligence and computer aided diagnosis.

Conclusion

Physicians are recognizing the need to utilize the latest in information technology. Computer sales are continually escalating. Computer systems are more accessible and powerful today than ever before. In the future, every medical practitioner will have to interact with some kind of computer on a daily basis. Billing patients, conferring with colleagues, scheduling office appointments and hospital commitments will all be handled in this way. For today's medical offices, THE FUTURE IS NOW! □

Glossary of Useful Computer Terms

(taken from Computers and Programs Magazine, February 1984, p. 157)

ASCII — American Standard Code for Information Interchange

BASIC — Beginners All-purpose Symbolic Instruction Code. Developed at Dartmouth College as a simplified and interactive version of FORTRAN. This language was used to provide students ready access to a powerful computer from numerous locations across the campus. Although the language was never standardized (a standard is currently being considered), it quickly became and remains the most popular language for microcomputers.

Baud — A measure of the rate of speed at which digital data is transmitted in bits per second.

Bit — Acronym for Binary digIT. Represents one of two binary states, either one or zero. Universally used in electronic systems to encode information, commands and data. Bits are usually grouped in nybbles (four), bytes or words (eight), and larger units. An eight-bit microprocessor processes bits in chunks of eight, a 16-bit microprocessor in chunks of 16 and so on.

Byte — A group of bits, usually eight, universally used to represent a character. There are any one of up to two nybbles in a byte. One byte can represent 256 characters.

Computer — A general-purpose computing system whose minimum configuration is a CPU, memory, and input/output (I/O) capability.

CPU — Abbreviation for Central Processing Unit. Part of the computer responsible for processing data and storing data in and retrieving it from memory. Often referred to as the "brain" of the computer.

CRT — Cathode ray tube. This is the most common form of a computer display screen. It may be a television set or a video monitor, or a slightly modified version of these display devices.

Database — Systematic organization of data to permit easy access to desired information.

Disk — A flat, circular magnetic storage device that operates much like a phonograph record. To differentiate between the audio and computer media, spelling is different — disc for audio, disk for computers.

Diskette — A term often used to identify a "floppy disc" magnetic storage disk.

Display — A computer output device to show alphanumeric and/or graphics data. In personal computing, the display is usually a TV-like video screen, but it can be a printout from a hard-copy printer.

Floppy disk — A magnetic medium used for mass storage of data. Flexible disks are most commonly available in 5-inch and 8-inch sizes; single - and double-density formats. This term is used to describe the magnetic disk medium and its prtective jacket.

Hard disk — A mass-storage magnetic medium that uses a rigid-material disk for mass storage of data. Usually nonremovable, hard disk systems are faster and can store many times more data than is possible on same-size floppy disks. The disk itself is housed in an hermetically sealed enclosure, along with the read/write head, to insure against contamination.

Hardware — Describes all items in a computer system that are not software. Includes circuit boards, integrated circuits, transistors, discrete components, etc.

Interface — An electronic or software device used to mate a computer and its peripherals with the outside world.

I/O — Input/Output. Refers to the paths by which information enters a computer system (input) and leaves the system (output). Traditional input device is a keyboard although some computer systems utilized joysticks, a mouse, touch sensitive screens, or other similar devices. The usual output device on modern computers is a video screen and/or a printer.

Kilobyte (Kb or K) — Term used to denote 1000 bytes, with 1K = precisely 1024 bytes.

Load — A term that indicates the transfer of data from a storage location, such as a disk or tape, into a computer.

Megabyte (Mb) — A term used to indicate millions of bytes; 1 megabyte (1 Mb) = 1,048,576 bytes, or approximately 1000 K.

Microcomputer — An integrated, complete small computer system built around a microprocessor (CPU), memory and input/output interfaces, and containing a power-supply. All personal computers are microcomputers.

Microprocessor — The brain of any computer. Performs all of the mathematical and logical operations necessary for the functioning of a computer system (see CPU).

Modem — Acronym for MOdulator/DEModulator. A device used to interface a computer with a telephone line, thereby converting digital information into analog format and vice versa.

Operating system — A program or collection of programs used to manage the hardware and logical functions of a computer system.

Parallel port — An input/output port in a computer through which data is transmitted and received in multiple bits at a time (usually eight). The two most popular ports of this type are the Centronics and IEEE488.

Personal Computer — A low-cost, very compact computer designed for the individual user without requiring access to a large computer.

Program — A list of user-specified instructions that tells a computer to perform a specific programming task. Programs can be written in machine language, assembly language and high-level language.

RAM — Abbreviation for Random-Access Memory. A volatile type of temporary storage device that can be written to by the user. Any data byte stored in RAM can be directly retrieved simply

by entering its address. Data stored in RAM normally is irretrievably lost when power is shut down.

Serial port — An input/output port in a computer through which data is transmitted and received one bit at a time. In most cases in personal computers, serial data is passed through an RS-232C serial interface port.

Software — A term used to denote a program or group of programs that run on a computer system. Often prepackaged by manufacturers on magnetic media such as floppy disks or tape, software is usually designed to perform multiple, interrelated processing tasks (see Program).

Turnkey — Used to describe computer systems that are complete and ready-to-go on delivery. A turnkey system includes software and hardware, and is usually targeted for a specific market or function.

Word processor — A text editor system for writing, formatting and storing word-intensive documents such as letters, reports, books and notes prior to printing. Often includes programs to merge mailing lists with form documents and to correct spelling.

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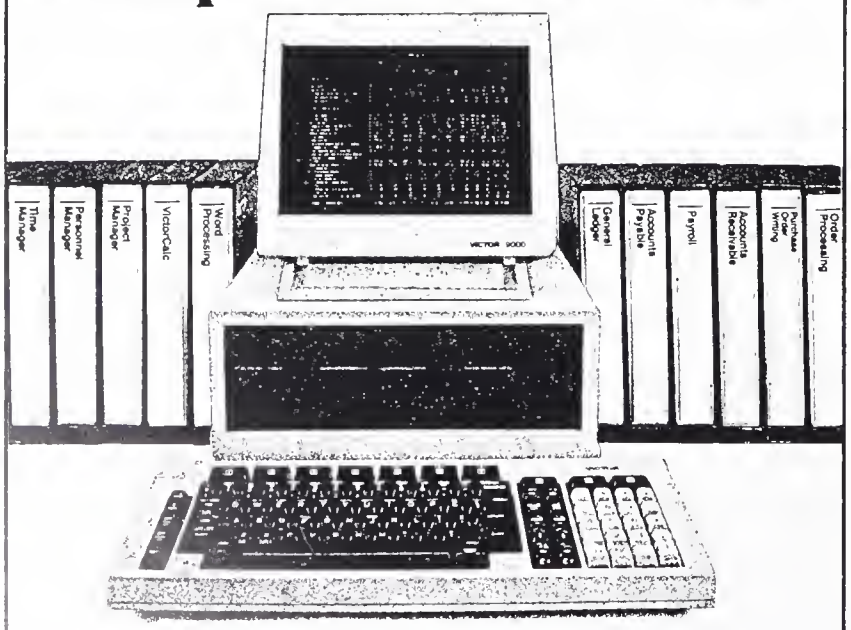

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COMMENTARY

Life After Medical School

Barry Simon 8T5

"A specialist differs from a non-specialist in that the former learns more and more about less and less, until eventually he knows everything about nothing; whereas the latter learns less and less about more and more until eventually he knows nothing about everything."

Not for four years but a lifetime is a motto that should reflect joining the fraternity of medicine. Each step brings into view the endless more flights that one is able to scale. Upon completion of medical school we will soon be faced with the option of choosing from a multitude of specialties. Much like a kid with his nose pressed against a candy store window, we must attempt to choose which is our favorite sweet. Over sixty percent will decide that five years of education has been sufficient and that they would prefer to spend their time keeping up with all the sweets available, but rarely indulging in any of them. This choice or freedom to explore is an individual decision and it is the mechanism of this choosing process that will be investigated.

The first four years of medical training are much like the early years of childhood according to Freud. We forget most of what we learned, but we have a gut feeling that many of the moments were terrifying experiences. For example, when purchasing a bed and one finds oneself being asked questions by the salesman at the bedside about one's room and there is this sudden need to change one's pants (or skirts — not that I'm saying that women do not have a right to wear pants or for that matter that men are unable to tastefully wear a skirt). These moments act as helpful indications of the latent anxiety to these early years.

These early magical years of medical school can be divided into a series of stages of psychosocomial development: a series of stages in each of which the student's central motivation was to gratify the drive for abuse in a different bodily zone —the mouth, the anus, and the genitals. For at each stage the child is forced to deal with a conflict between his or her own drive for gratification and the restrictions that the medical environment places on that gratification.

During the first year of medical school, the fetus undergoes many changes and is provided the basic skills to survive but only with assistance from its environment. The beginning of the second year is heralded by the primal scream of birth into the hospital world. Second year medical school, constitutes *the oral stage* in which the infant must "suck-up" in order to survive; accordingly their first two years of undergraduate education have equipped them with this technique. Fixation at the oral stage results in a syndrome characterized by brown lips and a severe kyphosis.

By the third year of "life", the medical school student shifts his or her libidinal attention from the mouth down to the other end of the alimentary canal. In the anal stage the major sources of physical pleasure are the retaining and expelling of facts. In the retention of facts, the pleasurable stimulus is the mild pressure of the knowledge that you know the answer, while in the expulsion of these facts, the pleasure is in the tension that appears on the faces of one's fellow students with listing of the correct response. The manifestations of anal fixation is the clinician. The final three months of third year medical school are *the phallic stage*, where the focus is shifted to the genitals and the only sensual pleasure that one has time for is derived from the stroking and handling of one's own genitals. By the end of the phallic stage the student begins to develop a strong sense of self, of independence and autonomy due to the completion of one's classroom learning of clinical medicine.

Fourth year, internship and one's residency are known as the *latency period* in which, as the term indicates, socomial impulses appear latent. One is too exhausted to have a libido for anything and any attention is directed toward the mastery of medical skills. After this period of presumably asexual behavior (depending on one's friendship with the nursing staff) socomial strivings are awakened as the doctor now enters his puberty. Following years of struggling with external abuse, one is now able to call oneself a staffman. In puberty individuals begin rechannelling their libidinal energy in this need to "screw" everyone. Young unsuspecting medical students are easy prey as well as the general public who accept their word as fact. It is only at the end of this final phase of development that the staffman attains full maturity upon realizing that what he wishes to "do to a few" the Trudeau government is doing to everyone in this country.

Essential to this developmental model is a strange breed known as the surgeon. Surgery is considered by many (most of them surgeons) to be the elite team who gracefully ride on to the scene when all other treatment fails. The only exception being the ENT specialists who hang around school yards listening for children who breathe loudly through their mouths so that one more unsuspecting child can have his adenoids out. What kind of people become surgeons? The need to be physically aggressive is easily carried out with a knife in one hand and an unconscious victim who is a passive recipient of all one's unconscious energy. Add to this a masochistic nature exemplified by his work hours and one has created the general surgeon. Each specialty reflects a further unusual quality. The orthopedic surgeon works away with his hammer, saws and nails. This is quite appropriate as most of them believe themselves to be direct descendents of a more

universal carpenter. Ophthalmologists are a rare breed as they are physicians who could not get into dentistry. They are just another victim of dental school admission standards where no man with an I.Q. of greater than fifty shall drill a cavity.

Urologists are truly a Freudian playground. You do not need a group of professionals to tell sixty and seventy year old men that their sex organ does not work as well as it used to. For those who take twenty minutes to empty their bladder urologists offer the opportunity to have their urine flow out — whenever they bend over to tie their shoes.

Finally, the obstetrician, who has recently been under attack for specializing in a process that was once considered natural. Their role is once again guaranteed in society, following a few natural childbirths without anaesthetics. The word gets around fairly quickly that there is nothing "natural" about a "fat" lady biting off her lower lip and foaming at the mouth. Thus the obstetrician's role is safe and with their protection we can all breathe a sigh of relief for our little children's safety from men in long grey trench coats offering them candy.

Based upon this revolutionary approach to understanding the psychosocomial model what can we predict for the future of medicine. It appears that by 1995 we will all be working for our government on a fixed civil servant's salary. Underachievers will thrive in medicine and the curriculum will have to teach the basic civil servant's course of "49 things you didn't know you could do with a paperclip". Finally, with the wonderful pension plans that are fixed to the cost of living, month-long vacations and retirement at age 45 at full salary, we will have the unusual opportunity of educating pediatric neurosurgeons so that they will retire in the same year they begin to practice.

Regardless of who is in charge, medicine will always be a series of endless stages and with each a new challenge to solve the timeless question of : "Why couldn't I just have been a plumber?"□

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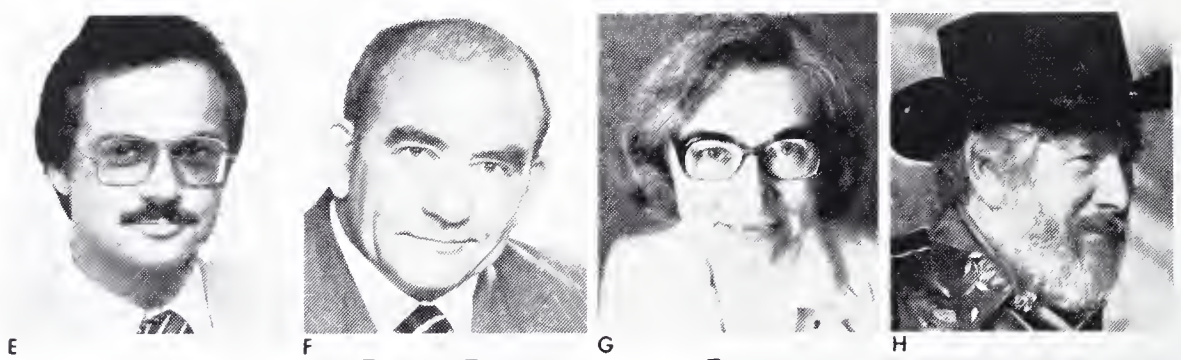
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Dalacin® C Phosphate Phosphate S.S.

Recommended Applications

Action: Clindamycin exerts its antibacterial effect by causing cessation of protein synthesis and also by causing a reduction in the rate of synthesis of nucleic acids.

Indications: Dalacin C Phosphate (clindamycin phosphate) is indicated for the treatment of infections where the oral route is not indicated or feasible.

Dalacin C Phosphate is indicated in the treatment of serious infections due to sensitive anaerobic bacteria such as Bacteroides species, peptostreptococcus, anaerobic streptococci, Clostridium species and microaerophilic streptococci.

Dalacin C Phosphate is also indicated in serious infections due to sensitive Gram-positive organisms (staphylococci, including penicillinase-producing staphylococci, streptococci and pneumococci) when the patient is intolerant of, or the organism resistant to other appropriate antibiotics.

Contraindications: The use of Dalacin C Phosphate (clindamycin phosphate) is contraindicated in patients previously found to be hypersensitive to this compound, the parent compound, clindamycin, or clindamycin palmitate. Although cross-sensitization with Lincocin® (lincomycin hydrochloride) has not been demonstrated, it is recommended that Dalacin C Phosphate not be used in patients who have demonstrated lincomycin sensitivity.

Until further clinical experience is obtained, Dalacin C Phosphate is not indicated in the newborn (infants below 30 days of age), or in pregnant women.

Warnings: Some cases of severe and persistent diarrhea have been reported during or after therapy with Dalacin C Phosphate (clindamycin phosphate). This diarrhea has been occasionally associated with blood and mucus in the stools and has at times resulted in acute colitis. When endoscopy has been performed, some of these cases have shown pseudomembrane formation.

If significant diarrhea occurs during therapy, this drug should be discontinued or, if necessary, continued only with close observation. Significant diarrhea occurring up to several weeks post-therapy should be managed as if antibiotic-associated.

If colitis is suspected, endoscopy is recommended. Mild cases showing minimal mucosal changes may respond to simple drug discontinuance. Moderate to severe cases, including those showing ulceration or pseudomembrane formation, should be managed with fluid, electrolyte, and protein supplementation as indicated. Corticoid retention enemas and systemic corticoids may be of help in persistent cases. Anticholinergics and antiperistaltic agents may worsen the condition. Other causes of colitis should be considered.

Studies indicate a toxin(s) produced by Clostridia (especially Clostridium difficile) may be a principal cause of clindamycin and other antibiotic-associated colitis. These studies also indicate that this toxigenic Clostridium is usually sensitive *in-vitro* to vancomycin. When 125 mg to 500 mg of vancomycin were administered *orally* four times a day for 5 – 10 or more days, there was a rapid observed disappearance of the toxin from faecal samples and a coincidental recovery from the diarrhea.

It should be noted that serious relapses have occurred up to one month after apparently successful treatment. A relatively prolonged period of continuing observation is therefore recommended.

Precautions: Dalacin C Phosphate (clindamycin phosphate), like any drug, should be prescribed with caution in atopic individuals.

Dalacin C Phosphate must be diluted for intravenous administration. (See Dosage and Administration)

The use of antibiotics occasionally results in overgrowth of nonsusceptible organisms – particularly yeasts. Should superinfections occur, appropriate measures should be taken as dictated by the clinical situation.

As with all antibiotics, perform culture and sensitivity studies in conjunction with drug therapy.

Since abnormalities of liver function tests have been noted occasionally in animals and man, periodic liver function tests should be performed during prolonged therapy. Blood counts should also be monitored during extended therapy.

Dalacin C Phosphate may be used in anuretic patients. Since the serum half-life of clindamycin in patients with impaired hepatic function is greater than that found in normal patients, the dose of Dalacin C Phosphate should be appropriately decreased. Hemodialysis and peritoneal dialysis are not effective means of removing the compound from the blood. Periodic serum levels should be determined in patients with severe hepatic and renal insufficiency.

Adverse Reactions: *Local*

(a) *Intramuscular Injections:* Of 404 patients treated with Dalacin C Phosphate (clindamycin phosphate) intramuscularly (with a solution containing 150 mg/mL), six (1.5%) demonstrated local reactions as follows: Two complained of pain at the injection site, two demonstrated induration at the injection site and two developed sterile abscesses.

(b) *Intravenous Infusions.* Of 192 patients treated with Dalacin C Phosphate by intravenous infusion, 14 (7.3%) demonstrated local reactions. Eleven patients developed superficial thrombophlebitis and one patient developed both superficial and deep thrombophlebitis. The majority of these cases developed in conjunction with the use of indwelling I.V. catheters and it is difficult to know how much the drug contributed to the irritation. Two patients developed localized erythema, swelling and pain at the site of the infusion.

Systemic Side Effects: Twenty-eight patients of 596 treated with Dalacin C Phosphate (clindamycin phosphate) by either the intramuscular or intravenous routes developed systemic side effects as follows.

	Number of Patients
Rash	7
Urticaria	1
Pruritus	1
Fever, Leucocytosis	1
Nausea, with or without vomiting	1
Diarrhea (See also under "Warnings")	4
Hypotension	1
Hypertension	1
Shortness of Breath	1
Superinfection*	4
Cardiac arrest**	1
Bad or bitter taste in mouth	5

*Superinfection is a complication of antibiotic therapy in general and is not necessarily a true side effect of clindamycin phosphate.

**Due to underlying myocarditis in this patient.

Clinical and Laboratory Findings: Patients treated during clinical trials of Dalacin C Phosphate (clindamycin phosphate) were followed with clinical laboratory tests, including complete hematology, urinalysis and liver and kidney function tests. Some of these tests were abnormal initially and returned to normal during therapy with Dalacin C Phosphate, while others were normal initially and became abnormal during therapy. Overall evaluation of clinical laboratory values in these patients does not indicate that Dalacin C Phosphate therapy has a toxic effect on the hematopoietic, hepatic or renal systems. Transient elevations of serum transaminases have occurred in some patients, but other liver function tests (alkaline phosphatase, serum bilirubin) have not shown any tendency to increase and there have not been clinical signs of drug-induced hepatic toxicity.

Symptoms and Treatment of Overdosage: No cases of overdosage have been reported. No specific antidote is known. Doses as high as 1200 mg every six hours (4800 mg/day) by infusion for five days have been given without adverse effects.

DOSAGE AND ADMINISTRATION

Adults

Intramuscular Injection: 600 mg/day in 2 equal doses.

Moderately severe infections: 600 to 1200 mg/day in 2 or 3 equal doses.

Severe infections: 1200 to 2400 mg/day in 2, 3 or 4 equal doses. Intramuscular injections of more than 600 mg into a single site are not recommended.

Intravenous Administration: Dalacin C Phosphate (clindamycin phosphate) must be diluted prior to I.V. administration to a dilution of 300 mg in 50 ml of diluent (6 mg/ml) or more, and infused in not less than 10 minutes. Administration of more than 1200 mg in a single 1 hour infusion is not recommended. Dalacin C Phosphate should not be injected intravenously undiluted as a bolus.

Moderately severe infections: 900 to 1800 mg/day by continuous drip or in 2 or 3 equal doses, each infused over 20 minutes or longer.

Severe infections: 1800 to 2700 mg/day by continuous drip or in 3 or 4 equal doses, each infused over 20 minutes or longer. In life-threatening infections, doses of 2700 to 4800 mg/day by continuous drip or in 3 or 4 equal doses each infused over 20 minutes or longer may be given.

Dilution and infusion rates:

Dose	*Diluent*	*Time*
300 mg	50 ml	10 min.
600 mg	100 ml	20 min.
900 mg	150 ml	30 min.
1200 mg	200 ml	45 min.

Alternatively, drug may be administered in the form of a single rapid infusion of the first dose followed by continuous I.V. infusion as follows:

To maintain serum clindamycin levels	*Rapid infusion rate*	*Maintenance infusion rate*
Above 4 mcg/ml	10 mg/min. for 30 min.	0.75 mg/min.
Above 5 mcg/ml	15 mg/min. for 30 min.	1.00 mg/min.
Above 6 mcg/ml	20 mg/min. for 30 min.	1.25 mg/min.

Children: (Over one month of age)

Intramuscular injection: 10 to 15 mg/kg/day in 2, 3 or 4 equal doses.

Moderately severe infections: 15 to 20 mg/kg/day in 3 or 4 equal doses.

Severe infections: 20 to 30 mg/kg/day in 3 or 4 equal doses.

Intravenous Administration:

Moderately severe infections: 15 to 25 mg/kg/day by continuous drip or in 3 or 4 equal doses, each infused over 20 minutes or longer. In severe infections, it is recommended that children be given no less than 300 mg/day regardless of body weight. (Dilute Dalacin C Phosphate Sterile Solution in the same manner as for adults.)

Dilution and Compatibility:

4 ml (600 mg) Dalacin C Phosphate when diluted with 1000 ml of the following commonly used infusion solutions was found to be physically compatible and demonstrated no significant change in pH or antimicrobial potency over a period of 24 hours:

- Sodium chloride injection
- Dextrose 5% in water
- Dextrose 5% in saline
- Dextrose 5% in Ringer's Solution
- Dextrose 5% in half-strength saline plus 40 mEq potassium chloride
- Dextrose 2½% in Lactated Ringer's Solution (Hartmann's Solution)

Dalacin C Phosphate was not stable when added to Dextrose 5% in water plus vitamins. Therefore it is not recommended that Dalacin C Phosphate be mixed with any infusion solution containing B vitamins.

Supplied:

Dalacin C Phosphate contains the following per ml of sterile solution.

- Clindamycin phosphate equivalent to clindamycin base 150 mg
- Benzyl alcohol 5 mg
- Disodium edetate 0.5 mg
- Water for injection q.s.

When necessary the pH is adjusted with sodium hydroxide and/or hydrochloric acid to maintain a pH range of 5.5 to 7.0.

Dalacin C Phosphate is available in 2 ml and 4 ml ampoules.

NOTE: Do not store below 15°C.

Product Monograph available upon request. CE 1377 1C

834 REGISTERED TRADEMARK DALACIN TRADEMARK DALACIN C CE 3692 1L (CE 709)

PRODUCT OF Upjohn ANTIBIOTIC RESEARCH

MEMBER PMAC PAAB CCPP

THE UPJOHN COMPANY OF CANADA/865 YORK MILLS ROAD/DON MILLS, ONTARIO

Dalacin C Phosphate Sterile Solution
(clindamycin phosphate)

...the standard to which others are compared.

- Provides excellent penetration into infected abscesses.[2]
- Highly effective against gram-positive aerobes including penicillinase – producing Staphylococci.
- Highly effective against gram-positive and gram-negative anaerobes, in particular *Bacteroides fragilis*.
- After 10 years of clinical use, resistance development to *Bacteroides fragilis* is as low as 2%.[3]
- Has *never* been associated with any carcinogenic or mutagenic activity.
- May enhance the natural host defense system; has been shown to concentrate within polymorphonuclear leukocytes in vitro. These neutrophils in turn may act as an important antibiotic delivery system to the site of infection.[4]

1. R. Fekety, M.D., Drug Therapy Hospital, October 1982
   *In combination with an aminoglycoside.
2. Mouzas G.L., et al (1980) Brit J Clin Pract *34*:234
3. M.H. Yee, M.D. et al, JAMA, October 15, 1982, Vol. 248, No 15
4. M.S. Klempner et al, J. Inf. Dis., Vol. 144, No. 5, November 1981

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for complete prescribing information please see page _____

The Medical Alumni Association is the bridge between the graduates and the Faculty of Medicine, University of Toronto.

During your undergraduate years, the Association was involved with providing financial assistance (scholarships, bursaries, travel grants, fellowships, loans) as well as sponsoring programs that were of particular interest — General Practice Panel, Arts and Letters Committee, Undergraduate Affairs, Graduation Banquet, etc. Now that you have graduated, the Association is still able to offer financial assistance in form of bursaries and loans; as well as being your representative at the Faculty and University level.

At the Faculty level, there are two representatives on the Faculty Council, a representative on the Admissions Committee, and the Chairman of the Student Aid Committee is a representative on the Student Awards Committee.

At the University level, the Association has two representatives on the University of Toronto Alumni Association, two representatives on the College of Electors, and a representative on the Varsity Fund Executive Committee.

We are also represented on various Search Committees when Department Chairmen and the Dean of Medicine are being sought.

During the past three years the Association has been involved in collecting funds on behalf of the Faculty of Medicine (Update) to support and expand a Continuing Education program. This program will become increasingly more important if the College of Physicians and Surgeons decides to incorporate the need to re-license physicians every five years. Government funding has been decreased for existing programs, and there is no provision for the incorporation of new ones.

The Association is also involved in providing some impetus to five year reunions. Two letters will be sent free of charge, for each class celebrating their reunion. Every attempt is made to keep an up-to-date address list of all our graduates. Please remember to notify YOUR Medical Alumni Association of any address change.

The Association is governed by graduates who give their time and talent voluntarily. There is one full time employee. Donations given for Student Aid are used entirely for that purpose; and the donations given on behalf of the Faculty of Medicine Update are tuned over to the Faculty without any administrative charge. Trust funds are administered, without charge, following the direction of the donor.

If you are interested in serving on the Executive Committee, or would like to have your opinions voiced to the proper authorities, please do not hesitate to contact YOUR Medical Alumni Association.

Above all, consider it an honour to be invited to attend the Medical Alumni Association and to help those who are coming after you.

MEDICAL ALUMNI ASSOCIATION